THE PLASMA FRACTIONS MARKET

IN THE UNITED STATES

2001

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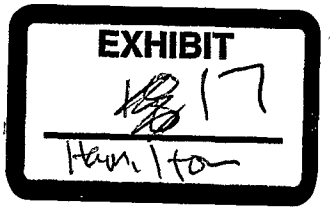
July 2002



INTRODUCTION

In 2002, The Marketing Research Bureau, Inc. began an extensive marketing research study to determine the major changes that have affected the plasma products market in the United States since the last report was published in 2001. This survey was part of an ongoing research effort to provide comparable data in other regions since the first report was completed in 1974.

Specific considerations were given to the market for polyvalent and hyperimmune globulin (IM and IV) products, albumin and plasma protein fraction, Factor VIII and IX concentrates, anti-inhibitor complex concentrates, alpha-1 antitrypsin, antithrombin III, and fibrin sealants. Recombinant Factors VIII and IX concentrates have been included in the study since the 1994 report. In 2000, the sales of Factor VII:a concentrate have been added, as well as those of a monoclonal antibody product (Respiratory syncytial Virus, RSV-MAB) which competes with a plasma-derived product (RSV immune globulin). Production volumes, prices, competitive actions, distribution, and regulatory aspects were analyzed as they influence product availability and sales. Another objective of the study was to review plasma procurement and fractionation.

The following report was completed and delivered to domestic and international subscribing clients in July 2002.

The Marketing Research Bureau, Inc.

July 2002

EXECUTIVE SUMMARY

* In 2001, the U.S. plasma fractions market reached an estimated total of $2,033.6 million (plasma products only), a 17.4% increase over the previous year. This growth was attributed primarily to strong IGIV sales (+24% in volume and dollars). IGIV sales now represent more than half of the U.S. plasma products market (51.2%). When including the recombinant Factors VIII, IX and VII:a products, the market reached $2.9 billion, a 16.6% increase over 2000 (excluding the sales of medicine's "Synagis" RSV monoclonal antibody).

* The resumption of full production activity by the fractionators after a succession of plant shut downs and slow downs, and the investments made to increase their capacity and yields brought a large volume of products to the market. This increase in capacity appears to be outstripping the market demand as prices have begun to slip in the first half of 2002. The U.S. fractionators are therefore competing more aggressively on the domestic and export markets.

* In August 2001, Alpha Therapeutic resumed full production after some two years of interruption and sporadic product lot releases. Using funds from Welfide, its parent company, Alpha underwent an ambitious program of production improvements and capital investments to meet FDA requirements. In October 2001, Welfide merged with Mitsubishi Tokyo, resulting in a new entity named "Mitsubishi Pharma." In mid-2002, Mitsubishi Pharma moved to offer Alpha Therapeutic for sale.

* As several fractionators acted to secure their long term supply of source plasma by acquiring plasma collection organizations during 2001 (Grifols/Seracare, 42 centers; CSL/Nabi, 47 centers, etc), the consolidation of the plasma industry appeared to take a new direction early in 2002. In February, Aventis and Bayer announced the signature of a letter of Intent stipulating that a majority stake of Aventis Behring would be acquired by Bayer. While the product portfolios and respective strengths of the two companies complement each other's, the issue of plasma supply may also have been one of the motives for this transaction.

* *In 2001, and through the first half of 2002, the shortage of recombinant Factor VIII diminished gradually in part because Bayer and Aventis Behring were able to release lots of "Kogenate FS" and "Helixate FS" at an increasing pace. In 2001, the larger quantity of Baxter's "Recombinate" and introduction of Wyeth's "ReFacto" available were not sufficient to offset the under-supply of Kogenate FS and Helixate FS, leading many hemophilia A patients to switch from these recombinant products to a plasma-derived product. As a result, unit sales of plasma-derived Factor VIII products went up markedly in 2001, jumping from 300 million units in 2000 to 450 million in 2001.*

The U.S. Plasma Fractions Market by Major Company from 1990 to 2001 (without recombinant Factors)

	Aventis Behring ($MM)	Bayer ($MM)	American Red Cross ($MM)	Baxter ($MM)	Alpha Therapeutic ($MM)	All Others ($MM)	Total Market ($MM)
1990	148.9	171.9	108.7	121.7	69.2	484.6	1,105.0
1992	195.4	195.6	145.0	146.6	111.4	368.0	1,162.0
1994	291.5	248.4	104.1	139.2	172.3	268.5	1,224.0
1996	242.2	249.5	155.8	172.6	219.5	270.7	1,310.2
1997	95.7	249.5	155.8	172.8	236.8	404.8	1,315.4
1998	117.3	272.7	240.5	269.6	242.8	352.2	1,495.1
1999	212.9	357.6	288.5	269.0	86.5	418.8	1,633.3
2000	291.1	376.2	291.3	376.8	39.9	350.7	1,726.0
2001	345.3	336.6	378.8	466.6	130.2	376.1	2,033.6

* *Baxter Bioscience was the market leader with 22.9% of total sales of plasma-derived products in 2001, followed by the American Red Cross with 18.6%, then Aventis Behring and Bayer each with about 17%. These four fractionators accounted for 75.1% of the U.S. market. When taking the sales of recombinant products into account, Baxter's market share jumped to 31.1%, due to strong sales of Recombinate. It was followed by Aventis Behring with 13.5% and Bayer, with 12.7%.*

* *Between 2000 and 2001, the average price of IVIG remained virtually unchanged (about $48 per gram for all products combined) but it went down by an estimated 5% to 10% or more during the first half of 2001, as increased production started pushing up inventories. Between 2000 and 2001, the price of albumin declined from $2.93 per gram ($36.65 per vial, 12.5 grams) to $2.72 per gram ($34.00 per vial) and edged down further during the first half of 2002. The price of plasma-derived coagulation Factor VIII concentrates remained essentially stable (+1.3%) while those of recombinant Factor VIII products increased by about 5%.*

The Plasma Fractions Market in the United States – 2001
Sales ($ MM) and Percent Change from 2000

Product	($ Million)	'01/'00
Polyvalent & Hyperimmune Globulin (IM)	$ 230.5	- 3.1%
Polyvalent Intravenous Immune Globulin (IGIV)	$1,041.9	+ 24.4%
Albumin and PPF (Fraction V)	$ 232.4	+ 6.7%
Plasma-derived Factor VIII	$ 284.0	+ 44.9%
Recombinant Factor VIII	$ 552.2	+ 10.9%
Factor IX & Factor IX Complex (plasma)	$ 49.2	+ 66.6%
Recombinant Factor IX	$ 133.2	- 5.4%
Activated Factor IX Complex Concentrate (plasma)	$ 59.7	- 3.4%
Recombinant Factor VII:a	$ 190.0	+ 55.1%
Antithrombin III	$ 2.7	- 45.5%
Alpha-1 Antitrypsin	$ 89.2	- 17.1%
Fibrin Sealant	$ 42.9	+ 3.7%
Total with rFVIII, rFIX, and rFVII:a	$2,908.9	+ 16.6%
Total without rFVIII, rFIX, and rFVII:a	$2,033.6	+ 17.4%

* *Reversing a five year trend, albumin demand appeared to increase in 2001, gaining +15.1% in volume and +6.7% in dollars. Some inventory may have been held unsold by distributors, as the manufacturers apparently released more than the market seems to have used, as some spot surveys suggested. Nonetheless, this turnaround may be in part attributed to the measures taken by the fractionators, as well as by the Plasma Protein Therapeutics Association (PPTA) to promote the use of albumin and to caution against overuse of plasma*

expanders. As it did last year, the American Red Cross dominated the albumin market with a 31.0% market share. Some 85.4 metric tons of albumin were used in the United States in 2001 (6,835 12.5 grams equivalents), representing 310 kilograms per million population .

* *About 21.7 metric tons of IGIV were used in the U.S. in 2001 for a value of over one billion dollars ($1,041.9 million), an impressive 24% increase in volume and value. Along with Canada, the United States is the country with the highest IVIG usage per capita, about 63.7 grams per thousand people. This is attributed to wide product awareness, extensive off-label usage, and accessibility to reimbursement for a therapy which is either more strictly controlled or not as affordable in other countries.*

* *In 2001, a total of 1.28 billion international units of Factor VIII were used in the U.S., or more than 100,000 international units per hemophilia A patient per year. The U.S. ratio of Factor VIII per population is now 4.3 international units per capita. In dollars, the market was worth $836.1 million, a 20% increase over the previous year. The recombinant products held 66.0% of the market in dollars, and 58.1% in units. The monoclonal antibody-purified products had a 24.2% market share (35.2% in units), and the remaining 9.7% was intermediate purity Factor VIII products (6.7% in units).*

* *In 2001, the continued demand for recombinant Factor VIII concentrates resulted in a 5.4% increase in their unit sales, and a 10.9% increase in dollars, as their prices went slightly up. The volume growth would have been probably higher, had there been no shortage which benefited the plasma-derived Factor VIII products: their sales jumped by +50.0%, and +52.0% in dollars. In 2001, Baxter continued to dominate the Factor VIII concentrate market (recombinant and plasma-derived combined) with an overall share of 68.8%. Aventis Behring followed with 13.1%, and the American Cross was third with 9.3%.*

* *The von Willebrand Disease (vWD) market increased by approximately 30% in volume and value to reach an estimated $81.4 million, or 128 Ristocetin co-Factor units. This growth was the outcome of the continued efforts of the National Hemophilia Foundation to reach vWD patients and direct them to appropriate treatment at Hemophilia Treatment Centers. This market continued to be dominated by Aventis Behring with nearly 80% market share. This company's "Humate P" is the only company with an approved indication since 1999, while Alpha Therapeutic was still awaiting FDA approval of the vWD indication for "Alphanate" in mid-2002. Alphanate was approved for vWD treatment in the UK and Italy earlier this year.*

* *Overall, the Factor IX concentrates market remained relatively stable (about +7.% both in units and dollars) in the past twelve months, with 260 million international units sold, for a total of $182.9 million. The plasma-derived products increased their market share (27.2%) as Alpha Therapeutic ramped up its production of "AlphaNine SD" and Mononine gained customers. Nevertheless Wyeth's "BeneFIX" (recombinant Factor IX) continued to largely dominate the market with 72.8% of total sales. "AlphaNine SD" sales increased to $18.2 million a 240% jump from 2000, as it was virtually out of the market that year. Sales of Factor IX complex concentrates (PCC) dwindled to $1.4 million.*

* *In 2001, the sales of "NovoSeven" (recombinant Factor VII:a) increased to $190.0 million (+55.1%), capturing 75.9% of the anti-inhibitor products market. The product did not cannibalize Baxter's "Feiba VH" which progressed by +8.3% to reach $52.3 million in sales, or 20.9% the market, leaving the remaining 3.2% to Nabi's "Autoplex T". Sales of Factor VIII and IX used to induce immune tolerance was estimated at $145.5 million. NovoSeven seems to have affected the sales of "Hyate:C", Ipsen's (formerly Speywood) porcine Factor VIII, the sales of which declined from about $20 million in 2000 to some $7 million in 2001. This decline was also caused by manufacturing problems.*

* *The fibrin sealant market posted a 18.3% volume increase between 2000 and 2001, as sales reached 460 liters. A price erosion (-12.3%) resulted in a smaller (+3.7%) increase in dollars. Baxter's maintained its leadership with 72.9% market share, while Haemacure's share went slightly down from 30% in 2000 to 27.1% in 2001.*

* *The sales of Bayer's Alpha-1 Proteinase inhibitor went down by about 17.1% in volume and dollars, because of manufacturing problems through 2001. Some 5,000 patients suffering from congenital emphysema are now treated with "Prolastin." Several companies, notably Alpha Therapeutic, Aventis Behring and Baxter, are poised to introduce a product that will compete with Bayer, which itself is collaborating with the Scottish PPL Therapeutics to develop new products to succeed, or complement Prolastin.*

* *The sales results of the hyperimmune globulin products varied from one product to another for reasons intrinsic to each sub-market:*

The Hyperimmune Globulin Market in the United States – 2001
Sales (Units and $ MM) - Percent Change from 2000

	Sales	Change	
Product	($ Million)	Units	Dollars
Polyvalent intramuscular IG	2.8	- 37.2%	- 30.8%
RhoD Immune Globulin	74.7	- 22.5%	- 25.0%
Tetanus Immune Globulin	5.4	+ 50.%	+ 53.6%
Rabies Immune Globulin	41.6	- 18.7%	- 10.4%
Hepatitis B Immune Globulin	37.8	- 2.5%	- 5.5%
Cytomegalovirus (CMV) IG	32.3	- 11.3%	- 11.3%
Varicella Zoster Immune Globulin	2.4	- 55.6%	- 59.8%
Respiratory Syncytial Virus (plasma-derived) Immune Globulin	0.9	- 50.0%	- 50.0%

* *Between 2000 and 2001, the volume of source and recovered plasma collected for fractionation went up by +14.3% and +9.7% respectively, and collectively reached approximately 13.1 million liters. The volume of plasma exported from the U.S. jumped from 5.2 million to 6.6 million liters (+26.5%)*

* *In the coming months, the U.S. plasma fractions market may experience a growing and crippling dichotomy between the fractionators' excessive plasma throughput and production, and a fairly stable demand for finished product, resulting in depressed prices and lower profit margins. Some relief is expected to come from higher export revenues, boosted by a favorable exchange rate of the US dollar, and more aggressive competition on the international markets. As the safety issues are partially resolved – to the extent allowed by current technologies - they gradually give way to questions of supply and demand. The industry's vertical integration and consolidation will insure better control over each phase of the production process and over costs, insure higher quality, and streamline operations. It may resolve some of the problems caused by the economic and medical boom of the last three decades.*

TABLE OF CONTENTS

TABLE OF CONTENTS
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TABLE OF CONTENTS
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TABLE OF CONTENTS
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TABLE OF CONTENTS
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LIST OF TABLES AND CHARTS

LIST OF TABLES AND CHARTS
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THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

THE US PLASMA FRACTIONS MARKET - 2001
INCLUDING RECOMBINANT FACTORS

COMPANY	DOLLARS (MM)	MARKET SHARE	CHANGE 01/00
Bayer	370.821	12.7%	-17.6%
Bioport	0.200	0.0%	-99.8%
Alpha Therapeutic	130.218	4.5%	225.9%
Novartis	29.400	1.0%	-92.4%
Aventis Behring	392.050	13.5%	2.0%
Baxter	905.778	31.1%	27.0%
Ortho Clinical Diagnostics	61.200	2.1%	15.0%
American Red Cross	378.830	13.0%	30.0%
Aventis Pasteur	30.000	1.0%	-14.5%
Nabi	73.060	2.5%	3.5%
Haemacure	11.640	0.4%	-6.8%
Wyeth	165.200	5.7%	16.5%
Massachusetts Laboratory	3.958	0.1%	-61.6%
Novo Nordisk	190.000	6.5%	55.1%
MedImmune	33.200	1.1%	-92.9%
ZLB Bioplasma	133.418	4.6%	422.2%
Total	2,908.971	100.0%	-0.4%

THE US PLASMA FRACTIONS MARKET - 2001
WITHOUT RECOMBINANT FACTORS

COMPANY	DOLLARS (MM)	MARKET SHARE	CHANGE 01/00
Bayer	336.621	16.6%	-10.5%
Bioport	0.200	0.0%	-99.8%
Alpha Therapeutic	130.218	6.4%	225.9%
Novartis	29.400	1.4%	-3.6%
Aventis Behring	345.300	17.0%	16.4%
Baxter	466.578	22.9%	23.8%
Ortho Clinical Diagnostics	61.200	3.0%	15.0%
American Red Cross	378.830	18.6%	30.0%
Aventis Pasteur	30.000	1.5%	-14.5%
Nabi	73.060	3.6%	3.5%
Haemacure	11.640	0.6%	-6.8%
Genetics Institute	0.000	0.0%	N.A.
Massachusetts Laboratory	3.958	0.2%	-61.6%
Novo Nordisk	0.000	0.0%	N.A.
MedImmune	33.200	1.6%	-13.2%
ZLB Bioplasma	133.418	6.6%	422.2%
Total	2,033.621	100.0%	17.4%

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

BREAKDOWN BY PRODUCT AND BY COMPANY WITH RECOMBINANT FACTORS (MILLION DOLLARS) - 2001

PRODUCT	AVENTIS BEHRING	ALPHA THERAP.	AMERICAN RED CROSS	BAXTER	BAYER	Nabi	OTHERS	TOTAL	CHANGE 01/00
IGIM	-	-	-	-	37.2	65.1	128.2	230.5	-65.3%
IGIV	155.3	76.5	236.6	242.3	190.4	-	141.0	1,041.9	24.4%
Fraction V	42.9	22.9	72.0	59.9	12.6	-	22.2	232.4	6.7%
Factor VIII	163.8	12.0	70.3	519.2	38.8	-	32.0	836.1	20.5%
Factor IX	30.1	18.8	-	0.8	-	-	133.2	182.9	6.8%
aPCC	-	-	-	52.3	-	6.0	190.0	250.3	37.4%
Antithrombin III	-	-	-	-	2.7	-	-	2.7	-45.5%
Alpha-1 Antitrypsin	-	-	-	-	89.2	-	-	89.2	-17.1%
Fibrin Glue	-	-	-	31.3	-	-	11.6	42.9	3.7%
Total '01	392.1	130.2	378.8	905.8	370.8	73.1	658.2	2,909.0	-0.4%
Total '00	384.3	40.0	291.3	713.4	449.8	70.6	972.0	2,921.3	
Change '01/00	2.0%	225.9%	30.0%	27.0%	-17.6%	N.A.	-75.0%	-0.4%	

* Included in "Others" in 1998

BREAKDOWN BY PRODUCT AND BY COMPANY WITH RECOMBINANT FACTORS (PERCENT) - 2001

PRODUCT	AVENTIS BEHRING	ALPHA THERAP.	AMERICAN RED CROSS	BAXTER	BAYER	Nabi	OTHERS	TOTAL
IGIM	-	-	-	-	10.0%	89.1%	19.5%	7.9%
IGIV	39.6%	58.7%	62.4%	26.7%	51.3%	-	21.4%	35.8%
Fraction V	10.9%	17.6%	19.0%	6.6%	3.4%	-	3.4%	8.0%
Factor VIII	41.8%	9.2%	18.6%	57.3%	10.5%	-	4.9%	28.7%
Factor IX	7.7%	14.5%		0.1%	-	-	20.2%	6.3%
aPCC	-	-	-	5.8%	-	10.9%	28.9%	8.6%
Antithrombin III	-	-	-	-	0.7%	-	-	0.1%
Alpha-1 Antitrypsin	-	-	-	-	24.0%	-	-	3.1%
Fibrin Glue	-	-	-	3.5%	-	-	1.8%	1.5%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

BREAKDOWN BY PRODUCT AND BY COMPANY WITHOUT rF VIII & IX (MILLION DOLLARS) - 2001

PRODUCT	AVENTIS BEHRING	ALPHA THERAP.	AMERICAN RED CROSS	BAXTER	BAYER	Nabi	OTHERS	TOTAL	CHANGE 01/00
IGIM	-	-	-	-	37.2	65.1	128.2	230.5	-3.1%
IGIV	155.3	76.5	236.6	242.3	190.4	-	141.0	1,041.9	24.4%
Fraction V	42.9	22.9	72.0	59.9	12.6	-	22.2	232.4	6.7%
Factor VIII	117.1	12.0	70.3	80.0	4.6	-	-	284.0	44.9%
Factor IX	30.1	18.8	-	0.8	-	-	-	49.7	68.6%
aPCC	-	-	-	52.3	-	8.0	-	60.3	1.0%
Antithrombin III	-	-	-	-	2.7	-	-	2.7	-45.5%
Alpha-1 Antitrypsin	-	-	-	-	89.2	-	-	89.2	-17.1%
Fibrin Glue	-	-	-	31.3	-	-	11.6	42.9	3.7%
Total '01	345.3	130.2	378.8	466.6	336.6	73.1	303.0	2,033.6	17.4%
Total '00	296.7	40.0	291.3	376.8	376.0	70.6	280.7	1,732.0	
Change '01/00	16.4%	225.9%	30.0%	23.8%	-10.5%	N.A.	8.0%	17.4%	

* Included in "Others" in 1998

BREAKDOWN BY PRODUCT AND BY COMPANY WITHOUT rF VIII & IX (PERCENT) - 2001

PRODUCT	AVENTIS BEHRING	ALPHA THERAP.	AMERICAN RED CROSS	BAXTER	BAYER	Nabi	OTHERS	TOTAL
IGIM	-	-	-	-	11.1%	89.1%	42.3%	11.3%
IGIV	45.0%	58.7%	62.4%	51.9%	56.5%	-	46.5%	51.2%
Fraction V	12.4%	17.6%	19.0%	12.8%	3.7%	-	7.3%	11.4%
Factor VIII	33.9%	9.2%	18.6%	17.2%	1.4%	-	-	14.0%
Factor IX	8.7%	14.5%	-	0.2%	-	-	-	2.4%
aPCC	-	-	-	11.2%	-	10.9%	-	3.0%
Antithrombin III	-	-	-	-	0.8%	-	-	0.1%
Alpha-1 Antitrypsin	-	-	-	-	26.5%	-	-	4.4%
Fibrin Glue	-	-	-	6.7%	-	-	3.8%	2.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

1) PLASMA COLLECTIONS

In 2001, the total volume of plasma fractionated into therapeutic products was about 13.2 million liters in the United States, a 13.5% increase from 2000. This included about 10.9 million liters of source plasma (+14.3% from the previous year) and 2.1 million liters of recovered plasma (+9.7%). The increase in plasma collections was attributed to higher unemployment, and the need for some low income people to complement their revenues by donating plasma.

Nearly all the U.S. commercial plasma collection centers are affiliated to the Plasma Protein Therapeutics Association – Source, or "PPTA-Source" (formerly called "American Blood Resources Association", or ABRA), the industry trade group. In 1991, ABRA set up a program called "Quality Plasma Program" (QPP) aimed at improving the quality and safety of the source plasma, especially for foreign customers who were concerned about the remuneration of plasma donors. Initially, this program was voluntary, and soon became mandatory for all the ABRA members. Today, virtually all the plasma collection centers members of PPTA-Source are QPP-certified. Most of those which are not QPP-certified collect plasma for diagnostic or other purposes. To qualify for QPP certification, a center must meet certain standards pertaining to the physical aspects of the collection facility, the training and qualifications of the staff, and the implementation of specified donor screening and of plasma testing procedures.

A typical plasma collection center conducts some 32,000 plasmapheresis procedures per year on average, generating some 30,000 liters of plasma per year. Some centers can generate as much as 100,000 liters of source plasma per year. The centers operated by PlasmaCare, Aventis Bio-Services and BioLife have reportedly larger collection volumes than the other organizations. The centers which collect hyperimmune plasma only collect a few thousand liters per year because the number of specialty donors is lower. On the other hand, these centers generate more revenue per donor because of the difference in the prices of hyperimmune and source plasmas. The plasma collection sector comprises two segments:

- The plasma collection centers owned and operated by the fractionators (Alpha Therapeutic, Aventis Bio-Services, and BioLife (formerly Baxter/Hyland/Immuno),

- The "independent" plasma collection organizations collecting plasma for American and foreign fractionators on a contractual basis, such as Life Resources, Nabi, Serologicals, SeraCare, Sera-Tec Biologicals.

1.1) CONSOLIDATION OF THE PLASMA COLLECTION SECTOR

The plasma collection sector has undergone a rapid consolidation in the last two years as fractionators acquired the largest independent organizations in a move to control their supply of plasma. This trend began in mid-2000 when Aventis Behring purchased 47 source plasma collection centers from Serologicals (which were operating under the name "Seramed") for $21.4 million. In the first half of 2001, three important acquisitions were made: Grifols bought SeraCare (42 centers), Baxter acquired Sera-Tec (80 centers), and CSL acquired 47 centers from Nabi.

As a result, over half of the plasma centers (216 out of 416) changed hands, going from four independent companies (Serologicals, Sera-Tec, SeraCare, and nabi) to four fractionators, two based in the United States (Aventis Behring and Baxter), and two outside the U.S. (Grifols and CSL/ZLB Bioplasma).

Consolidation of the Plasma Collection Sector

Date	Seller	Buyer	Number of Centers	Total Price $(MM)	Price PerCenter $(MM)
Aug-00	Serologicals	Aventis Behring	47	21.4	0.46
Feb-01	Sera-Tec	Baxter (BioLife)	80	250 Est.	3.1 Est.
Jun-01	SeraCare	Grifols	42	147.5	3.51
Aug-01	Nabi	CSL Ltd.	47	152.0	3.23
Total			216	320.9	1.49

The volume of plasma collected by these companies represents about 86% of the total source plasma collected in the country, and over two thirds (71%) of the total plasma used for fractionation (source and recovered plasma combined).

The vertical integration of the industry has been recently prompted by a need to exercise full control of every step of the manufacturing process, from the plasma donation to the finished product because of the increasingly stringent regulations.

The integration of the plasma supply and processing has also been motivated by the need to properly respond to challenges posed by the new requirements related to the screening of donors and plasma donations testing, as well as a desire to insure a sufficient quantity of plasma in the years to come, and to avoid the risk of possible BSE-transmission if they were to use some European plasma.

Furthermore, as Grifols and ZLB Bioplasma are both FDA-licensed, it is essential for them to guarantee a source of U.S. plasma if they want to sell their finished products in the U.S. The other major commercial European fractionators (Biotest, Kedrion and Octapharma) also rely on U.S. plasma but can use other sources of plasma because their products are not commercialized in the United States.

In 2001, several plasma collection organizations, including BioLife, Life Resources, Plasma Care and SeraCare, have announced plans for the construction of new collection centers.

PLASMA COLLECTIONS IN THE UNITED STATES FROM 1997 TO 2001
BREAKDOWN BY ORGANIZATION

Number of Centers in 2001	Organization	2001 Volume collected (Liters)	2000 *** Volume collected (Liters)	1999 Volume collected (Liters)	1998 Volume collected (Liters)	1997 Volume collected (Liters)	Change 2001/2000
43	Alpha Therapeutic Corporation	1,575,000	1,600,000	1,650,000	1,820,000	2,100,000	-1.6%
80	Aventis Bio-Services	2,675,000	1,450,000	1,600,000	1,630,000	2,100,000	84.5%
-	Bayer	-	-	-	290,000	380,000	N.A.
56	Nabi/ZLB Plasma Services (from Sept. 2001)	1,750,000	1,400,000	1,490,000	1,900,000	2,100,000	25.0%
	SeraTec Biologicals	-	1,830,000	1,800,000	1,200,000	1,100,000	N.A.
17	Serologicals	150,000	630,000	850,000	1,050,000	1,100,000	N.A.
102	BioLife Plasma Services (formerly Baxter)	2,575,000	590,000	630,000	640,000	700,000	N.A.
17	Interstate Blood Bank Inc.	305,000	275,000	245,000	250,000	185,000	10.9%
5	Pyramid Biological Corporation Van Nuys	150,000	115,000	65,000	85,000	95,000	30.4%
22	Life Resources (DCI Biologicals)	450,000	355,000	365,000	330,000	300,000	26.8%
42	SeraCare	805,000	720,000	525,000	400,000	180,000	11.8%
9	PlasmaCare (Stough Enterprises)	290,000	205,000	245,000	240,000	260,000	41.5%
2	Trimar Plasma Corp. & Tri Cities	55,000	50,000	45,000	40,000	35,000	10.0%
2	Austin Bio-Med Lab	90,000	90,000	-	-	-	0.0%
19	Others *	10,000	5,000	10,000	270,000	570,000	100.0%
416	Total Source Plasma	10,680,000	9,515,000	9,540,000	10,145,000	11,205,000	14.3%
	ARC Recovered Plasma for fractionation	1,204,200	1,100,000	940,000	1,240,000	1,250,000	9.5%
	ABC, BCA & Other Recovered Plasma **	1,100,000	1,000,000	950,000	1,230,000	1,240,000	10.0%
	Total	13,184,200	11,615,000	11,430,000	12,615,000	13,695,000	13.5%

* Includes Cangono (3 centers), Biomedics, Saturn, Ortho, etc. In 2001, and others earlier: Allied Plasma, American Plasma, etc
Some of them collect plasma for diagnostic purposes only.
** Includes BCA and UBS
*** Restated

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

PLASMA PROCESSED BY THE U.S. FRACTIONATORS FROM 1996 TO 2001

Company	2001 Fractionation Throughput, In Process, and Export (Liters)	2000 Fractionation Throughput, In Process, and Export (Liters)	1999 Fractionation Throughput, In Process, and Export (Liters)	1998 Fractionation Throughput, In Process, and Export (Liters)	1997 Fractionation Throughput, In Process, and Export (Liters)	1996 Fractionation Throughput, In Process, and Export (Liters)	Change 2001 vs. 2000 (Percent)
Alpha Therapeutic	650,000	75,000	900,000	1,725,000	2,000,000	2,000,000	766.7%
Aventis Behring	1,250,000	1,200,000	1,100,000	900,000	600,000	2,000,000	4.2%
Baxter	1,260,000	1,255,000	1,320,000	930,000	950,000	1,000,000	0.4%
American Red Cross	750,000	1,160,000	910,000	1,000,000	1,000,000	1,000,000	-35.3%
Bayer	1,950,000	1,900,000	1,730,000	1,650,000	1,900,000	2,000,000	2.6%
Immuno	-	-	-	325,000	325,000	325,000	N.A.
Mass Biologic Lab	50,000	50,000	195,000	200,000	220,000	220,000	0.0%
Bioport	-	10,000	25,000	50,000	65,000	70,000	-100.0%
Precision Pharma (Vitex)	600,000	549,138	505,000	400,000	400,000	400,000	9.3%
Ortho Diagnostic	25,000	38,000	38,000	50,000	45,000	45,000	-34.2%
(a) Throughput	6,535,000	6,237,138	6,723,000	7,230,000	7,505,000	9,060,000	4.8%
(b) Hold/Transit/Test	72,437	180,000	85,000	293,000	1,256,000	1,023,000	N.A.
(a + b) Total in Process	6,607,437	6,417,138	6,808,000	7,523,000	8,761,000	10,083,000	3.0%
Exported from the U.S.	6,576,763	5,197,862	4,622,000	5,092,000	4,934,000	4,325,000	26.5%
Total	13,184,200	11,615,000	11,430,000	12,615,000	13,695,000	14,408,000	13.5%

Plasma Collections by Type of Plasma - United States

Total Source Plasma	10,880,000	9,515,000	9,540,000	10,145,000	11,205,000	11,890,000	14.3%
Total Recovered	2,304,200	2,100,000	1,890,000	2,470,000	2,490,000	2,518,000	9.7%
Total	13,184,200	11,615,000	11,430,000	12,615,000	13,695,000	14,408,000	13.5%

Licensed Plasma Centers in the United States - 1999/01

Company	*1981*	*1985*	*1990*	*1995*	*1999*	*2000*	*2001*
Alpha Therapeutic	28	38	49	62	52	43	43
Austin Biolab	-	-	-	-	2	2	2
Bayer	24	24	18	13	-	-	-
Aventis Bio-Services	15	15	21	32	33	34	80
Com. Bio-Resources	6	14	15	10	18	22	-
Life Resources	-	-	-	-	16	20	22
Nabi	-	28	31	78	62	56	56
Ortho	-	-	-	-	2	2	2
Pyramid Biological Corp.	-	-	-	-	5	5	5
Sera-Tec Biologicals *		-	26	41	75	80	-
BioLife (Baxter)	-	-	-	-	-	-	102
Serologicals	-	-	-	39	62	17	17
SeraCare	-	-	-	-	37	42	42
PlasmaCare	-	-	-	-	8	9	9
All Others	251	207	245	130	27	84	36
Total	381	377	448	443	425	416	416

*** Sold to Baxter in 2001

The "All others" group includes other smaller suppliers, plasma centers which produce hyperimmune plasma (Cangene, Ortho), or producers of plasma for the diagnostic industry.

In 1999, Bayer sold its 13 plasma centers to Sera-Tec. In 1994, Baxter sold its plasma centers to rely solely on contracts with independent plasma collection centers. However, when the company acquired Immuno in 1996, this company's plasma centers ("Community Bio-Resources" plasma centers) were transferred to Baxter. In 2001 Baxter increased its plasma self-reliance as it acquired the 80 plasma centers operated by Sera-Tec Biological for an estimated $250 million.

Several companies have indicated that they planned to open new plasma centers in the coming years, especially in the western part of the country. In mid-2000, Baxter officially announced that it would build 10 to 20 centers per year in the coming years in order to alleviate the

current shortage of source plasma. In 2001, SeraCare announced the opening of four new centers in the coming few months.

Number of Plasma Centers and of Source Plasma Collections in the United States

	Number of Commercial Plasma Collection Centers	*Total Collections Million of Liters*
1978	365	5.4
1982	344	5.8
1986	397	6.7
1990	448	7.3
1994	440	9.5
1996	454	11.8
1997	442	11.2
1998	427	10.1
1999	397	9.5
2000	416	9.5
2001	416	10.9

Although the recent mergers and acquisitions have further enhanced the degree of concentration of the plasma collection industry this trend is not over because the small independent collection operators do not have the resources to maintain an economically viable operation, in particular in view of the ever increasing safety requirements and regulations. For example, the need for qualified staff is such that a small collection center cannot financially sustain the minimum number of staff, which characterized the operation of a typical plasma center in the 1970's.

A source plasma donor is typically paid a $20-$30 fee per donation although this amount varies by region and center, and the number of donations. A typical plasma donor can earn $150 to $200 per month if he/she donated regularly. The donor compensation has increased in recent years in order to retain donors. Today, a new donor may be paid $35 for the first donation, and less for the following donations. Special incentives are offered to repeat donors as well as to those who give hyperimmune plasma. As regards the latter, the incentive may be higher

after a few donations because his/her antibody titer is higher, and the plasma is more valuable. Some community incentive programs are also implemented by some centers.

1.2) STEPS TO INCREASE THE SAFETY OF PLASMA DONATIONS

The Plasma Protein Therapeutics Association (PPTA) has initiated a number of measures aimed at improving the safety of the donated plasma, whether it is processed in the United States, or exported.

1.2.1) QUARANTINE FOR "PLASMA DONOR APPLICANTS"

Under the quarantine program, the donation of plasma by a first-time donor is held for up to six months ("Plasma Donor Applicant") before going into the fractionation process. If the "applicant donor" donates a second time during this six months period, and if the screening tests of the first donation are negative, the plasma can be used for fractionation.

However, if the donor does not return for a second donation during the quarantine period, his/her plasma cannot be used to manufacture therapeutic products.

The quarantine aims at ensuring that the plasma used for fractionation is safe and comes from donors who are committed to repeat donations. The quarantine is implemented by the collection centers since 1997. It is estimated that this has resulted in a 2% to 4% drop in total collections, as this was the percentage of first-time donors who never showed up for a second plasma donation during the quarantine period.

1.2.2) INVENTORY HOLD BY THE FRACTIONATORS

A plasma donation is held for a period of sixty days by the fractionator before it goes into the fractionation process. This period largely exceeds the "window" period of emergence of antibodies for HCV (28 days), HBV (25 days), and HIV (16 days), making it possible to retain the most recent donations from going into the manufacturing process if

a donor seroconverts during these sixty days. However, the inventory hold requires an important logistical effort from the fractionator, which impacts on the price of plasma. Since 1997, all the U.S. fractionators implement the sixty day inventory hold.

1.2.3) FIRST TIME DONORS

This measure, implemented in July 1997, eliminates the use of plasma from one-time donors. This standard requires that no units of plasma can be accepted for further processing unless the donor has successfully passed at least two health history interviews and two panels of all required screening tests within a six month period. Qualified donors are those who have passed through these criteria. Applicant donors, on the other hand, are individuals presenting themselves who have not been previously qualified as a donor in the past 6 months.

1.2.4) NAT TESTING

The Polymerase Chain Reaction (PCR) or Nuclear Amplification Technology (NAT) increases the sensitivity of testing, and reduces the window period of most infections. It is now implemented by all U.S. fractionators for HCV in the plasma pool.

1.2.5) NEW POLICY FOR DONOR SELECTION

In 2000, the American Red Cross announced its intention to stop taking blood from donors who have spent three months or more in the UK, and six months or more in Europe between 1980 and present. This measure, which is intended to reduce the theoretical risk of transmitting vCJD will eliminate an estimated 8% of current Red Cross blood donors. Current FDA requirements prohibit collection of blood donations from anyone who has spent six months or more in the UK from 1980 to 1996. This measure has de facto eliminated the "EuroBlood" program, forcing the New York Blood Center to rely on other sources and to increase blood collections

1.3) MAJOR PLASMA COLLECTION ORGANIZATIONS

1.3.1) INDEPENDENT PLASMA COLLECTION COMPANIES

Nabi Biopharmaceuticals
5800 Park of Commerce Blvd.
Boca Raton, FL 33498
Phone: (800) 642-8874
Fax: (561) 989-5899
Web: www.nabi.com

In recent years, Nabi has gradually shifted its focus from an independent plasma-collecting organization to increasingly become a pharmaceutical firm. In 2002, it changed its name to better reflect the new company focus. R&D efforts have allowed the company to combine the availability of a wide array of specialty plasma – or antibodies, as the company calls it – with the development of innovative products such as "Nabi-HB", its proprietary hepatitis B immune globulin for post-exposure prophylaxis of hepatitis B virus, and "Nabi-Altastaph", an high-titer immune globulin preparation against Staphylococcus aureus.

Until it sold 47 plasma centers to CSL for approximately $152 million in September 2001, Nabi was the country's largest independent plasma collection organization. It collected over 1.8 million liters of plasma from its 56 facilities. Along with Sera-Tec, it signed an agreement to supply plasma to BPL in 1998.

In mid-2002, Nabi's plasma fractionation facility in Boca Raton, Florida was approved by the FDA. It has a current fractionation capacity of 150,000 liters, and will be able to process 450,000 liters of plasma per year.

SeraCare
1925 Century Park East
Suite 1970
Los Angeles, CA 90067
Phone: (310) 772-7777
Fax: (310) 772-7770
Web: www.seracare.com

Based in Los Angeles, SeraCare owns and operates some 42 plasma collection centers throughout the U.S. In late 1998, it acquired plasma collection centers from "American Plasma", "Western States Plasma" and "Consolidated Technologies", and subsequently from Alpha Therapeutic. The company also manufactures and sells plasma-based diagnostics products, as well as controls and calibrators for the diagnostic test market. In June 2001, Grifols acquired the 42 centers operated by SeraCare for $147.5 million.

Sera-Tec Biologicals
10707 N. Broadway Extension
Oklahoma City, OK 73114
Phone: (405) 755-3930
Fax: (405) 755-4086

In April 2001, Baxter completed its acquisition of Sera-Tec Biological for an estimated $250 million. After it purchased Bayer's twelve plasma collection centers in 1999, "Sera-Tec" became the second largest independent plasma collection organization in the U.S. with 80 collection centers, all automated and QPP-certified. In 2000, Sera-Tec collected an estimated 1.8 million liters of plasma, and posted revenues over $100 million. This company supplies BPL with source plasma since July 1998.

Through one of its subsidiary, Sera-Tec Biological signed a five year contract with the Canadian company "Hemosol" for the supply of red blood cells for the production of the latter's "Hemolink" blood substitute.

Serologicals
5655 Spalding Drive
Norcross, GA 30092-2504
Phone: (800) 842-9099
Fax: (678) 728-2174
Web: www.serologicals.com

Serologicals is one the world's largest suppliers of hyperimmune plasma. It operates 17 centers collecting an estimated 150,000 liters of specialty plasma. As a result of financial difficulties experienced through 1999 the company sold 47 centers (operating under the name "Seramed") to Aventis Bio-Services for an estimated $21.4 million.

Until 2000, Serologicals operated 64 collection centers, 17 of which collected only hyperimmune plasma. Over the years, it acquired several collection centers from a number of small independent owners (13 centers from Gerant Industries in 1993, 11 centers from Am-Rho Laboratories, Southeastern Biologics, Plasma Management, Concho Biologics, and Simi Biological Resources in 1996, 16 centers from the "Nations Group" in 1997, etc) but financial and other difficulties led to the 2000 divestment.

All the plasma collection centers operated by Serologicals are QPP-certified. In December 1998, Serologicals acquired "Pentex Blood Proteins", from Bayer and expanded the facility in 2001. This company produces purified human and animal blood proteins to the diagnostic and biopharmaceutical industries.

Late in 2001, Serologicals acquired "Intergen" for a sum of $45 million. Intergen is a major supplier of biological products for the biotechnology and diagnostics industries. Its core products include bovine serum albumin, recombinant insulin, enzymes and other reagents for use in cell culture media. Specific components for diagnostics include defibrinated plasma, normal and disease state human sera and specialty human biologics, also supplied by the company.

Life Resources
71 S. Bedford Rd
Mt. Kisco, NY 10549
Phone: (718) 479-3300
Fax: (718) 217-4451

The 22 plasma centers of Life Resources are privately owned. The company collects an estimated 450,000 liters of source plasma, as well as small quantities of hyperimmune plasma. It reportedly supplies Octapharma and Bayer. Life Resources has announced that it would open three new plasma centers in 2003.

PlasmaCare
1128 Main Street
Cincinnati, OH 45210
Phone: (513) 621-8728
Fax: (513) 621-1618
Web: www.plasmacare.com

Plasmacare has operated 9 plasma centers in the Midwest for many years. It is privately owned, and plans to open a few new centers in the coming years. Total collection of source plasma are estimated at close to 300,000 liters, most of which is purchased by Bayer.

Interstate Blood Bank
3180 Old Getwell Road
Memphis, TN 38118
Phone: (901) 566-2000
Fax: (901) 566-2010

This company not only collects plasma but also whole blood and plasma for diagnostic usage. Total collections in 2001 were estimated at about 305,000 liters. It is privately-owned.

Pyramid Biological Corporation
6454 Vannuys Blvd.
Suite 111
Vannuys, CA 91404
Phone: (818) 785-1898
Fax: (818) 997-3235

This company is privately owned. It operates five plasma centers and collects an estimated 150,000 liters per year.

Others

Other private, independent plasma collection organizations include "Austin Biomed Laboratory" (approx. 90,000 liters), "Trimar & TriCities Plasma Corp." (55,000 liters), "Biomedics" (15,000 liters), etc.

1.3.2) PLASMA COLLECTION FACILITIES OWNED BY THE FRACTIONATORS

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2410 Lillyvale Avenue
Los Angeles, CA 90032
Phone: (800) 421-0008
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Mt. Kisco, NY 10549
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Cincinnati, OH 45210
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Fax: (513) 621-1618
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Los Angeles, CA 90032
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Aventis Bio-Services
1020 First Avenue
King of Prussia, PA 19406-1310
Phone: (610) 878-4000
Fax: (610) 878-4040
Web: www.aventis.com

Until its acquisition of the 47 source plasma collection centers from Serologicals in mid-2000, Aventis Bio-Services operated 33 plasma centers located in the Midwest, the Tennessee and Ohio River Valleys, and the Southwest. These centers, located in geographic areas considered to have lower viral marker rates, are generally near college towns. In 1996, the company merged the nine centers of "Associated Bioscience" which were collecting plasma for Behringwerke with "Plasma Alliance", Armour's plasma collection organization. In 2001, Aventis Bio-Services collected an estimated to 2.7 million liters in the United States.

BioLife Plasma Services (formerly Baxter)
1435 Lake Cook Road
Deerfield, IL 60015
Phone: (847) 940-5100
Fax: (847) 940-5150
Web:

With its acquisition of Immuno in 1996, Baxter acquired the 22 plasma centers of "Community Bio-Resources". In mid-2001, it acquired Sera-Tec Biologicals' 80 centers for $250 million, and plans to open several new centers in the coming years. In 2001, total collections were estimated to be close to 2.6 million liters in the United States.

ZLB Plasma Services
801 North Brand Blvd., Suite 1150
Glendale, CA 91203
Phone: (818) 244-2952
Fax: (818) 244-9952
Web: www.zlbusa.com

In September 2001, CSL completed its acquisition of 47 plasma centers from Nabi. The plasma collected by these centers continues to be delivered to Nabi's former customers (reportedly Bayer among others), until the contracts are re-negotiated, in 2003 and 2004. In the meantime, in 2001 and 2002, ZLB Bioplasma continued to purchase recovered plasma from blood centers for shipment to its fractionation plant in Bern, Switzerland.

1.3.3) PLASMA COLLECTED BY THE NON-PROFIT SECTOR

Some 2.3 million liters of recovered plasma were collected in 2001, almost equally shared between America's Blood Centers (ABC) and the American Red Cross (ARC).

America's Blood Centers (ABC)
725 15th Street NW
Suite 700
Washington, DC 20005
Phone: (202) 393-5725
Web: www.americasblood.org

In 2001, the ABC member blood centers reportedly collected about 6.8 million units of blood. This generated some 1.1 million liters of Fresh Frozen Plasma (FFP) for fractionation and 280,000 liters of FFP (one million units) for transfusion. It is estimated that the volume was broken down as follows:

- ZLB Bioplasma, Inc	730,000 liters
- Seraplex	120,000 liters
- Octapharma	250,000 liters
Total	1,100,000 liters

In 2000, ABC took an initiative to apply some of the QPP features to recovered plasma. Since recovered plasma differs markedly from source plasma, PPTA's QPP standards cannot be directly applied to recovered plasma, but the various organizations involved, as well as the FDA are working toward a compromise.

Blood collections have consistently increased in the recent years to meet the growing demand, estimated at 3% per year.

The September 11 attack has a substantial impact on blood donations as many donors gave blood in the ensuing weeks, in particular at the New York Blood Center. However, it is estimated that only 25% of the first time donors who showed up on this occasion came back. Even though the blood given after the attack could not be used, many of the platelets were used, and the plasma was frozen for subsequent fractionation.

American Red Cross (ARC)
1300 Wilson Boulevard
8th Floor
Arlington, VA 22209
Phone: (703) 312-5600
Fax: (703) 312-5772

In 2000/01, the ARC collected 6,790,448 units of whole blood, a slight increase from the previous year. 4,300,817 units of plasma (280 ml) were fractionated, and 1,429,022 units were used for transfusion.

Some two thirds of the plasma was fractionated by Baxter in Glendale, California, and one third by ZLB Bioplasma in Bern, Switzerland.

Plasma Units by Type of Use – 2001

Liters Fractionated	1,204,230
Liters used for Transfusion	400,126

In April 2002, the ARC announced that it would discontinue providing its pooled, solvent detergent-treated fresh frozen plasma product, "PLAS+SD", once current inventories were depleted. The reason for this decision was that "Precision Pharma" (formerly V.I. Technologies), the manufacturer of PLAS+SD was no longer licensed to produce it and the Red Cross no longer held the license to distribute it, following last year's divestiture of PLAS+SD operations along with its plasma fractionation plant in Melville, NY to a management-led investor group. The Red Cross had originally contracted with V.I. Technologies in 1998 to act as the exclusive supplier of this product to U.S. hospitals, blood centers and distributors.

In 2001, the ARC announced that it would no longer take blood from donors who spent three months or more in the UK, and six months or more in Europe between 1980 and present. In addition, the Red Cross would defer any potential donor who has received a blood transfusion in the UK at any time in the past. This measure was intended to reduce the theoretical risk of transmitting the prion causing variant Creutzfeldt Jakob disease (vCJD) through blood transfusion. It was expected to generate a loss of about 8% of the Red Cross blood donor pool. The measure was to be implemented in September 2001 but the September 11 attack led to a postponement to mid-2002.

Blood Centers of America (BCA)

875 Centerville Road
Building #1, Suite 15
Warwick, RI 02886
Phone: (401) 381-0600
Fax: (401) 391-0016

Blood Centers of America (BCA) is a cooperative of several non-profit regional Blood Centers formed in 1986 to provide economies of scale and to improve operational effectiveness. In 1999, BCA increased its membership to reach 29 blood centers, from 12 a year before. In 2000, the BCA centers collected and processed approximately xxx million units of whole blood.

In 1996, "Hemerica", a subsidiary of BCA, was formed as a stock corporation for the specific purpose to supply cellular components to the biotechnology industry. "Hemerica", had 11 centers in 1999. "Hemerica", supplies red blood cells for the production of Northfield's "PolyHeme" hemoglobin-based blood substitute. It also supplies Pharmacia & Upjohn for the production of "ATgam", a product develop to prevent organ transplant rejection. In 2001, BCA sent approximately 300,000 liters of plasma for fractionation

The breakdown of the recovered plasma procurement was estimated as follows: 720,000 liters collected by ZLB Bioplasma for fractionation by the company's plant in Bern, Switzerland (in addition to the ARC plasma), 250,000 liter purchased by Octapharma and 130,000 liters purchased by the Scottish National Blood Transfusion Service (SNBTS).

United Blood Services

6210 E. Oak Street
P.O. Box 1867
Scottsdale, AZ 85252
Phone: (800) 304-3064
Fax: (480) 675-7104

United Blood Services (UBS), a division of Blood Systems, operates 18 not-for profit community blood centers and serves over 500 hospitals in 15 states. In 2001, UBS collected 880,000 units of blood, generating approximately 151,000 liters of recovered plasma and about 222,000 units of fresh frozen plasma (approx. 280 mL) for transfusion. The organization also produced 83,000 plateletpheresis doases and 62,000 units of cryoprecipitate.

UBS is a member of ABC, and operates a not-for-profit subsidiary ("Biocare") which is a major distributor of RhoD immune globulin, among other products.

Alpine Biologics
33 King's Highway, Suite 1
Orangeburg, NY 10962
Phone: (845) 680-2400
Fax: (845) 680-9471

In 1994, "Alpine Biologics" was created as an agent of the Central Laboratory of the Central Laboratory of the Swiss Red Cross (ZLB). With the creation of ZLB Bioplasma in 2001, "Alpine Biologics" ceased its plasma procurement for the ZLB, as well as its distribution of ZLB products.

In addition to these organizations, the U.S. Armed forces collect an estimated 120,000 units of blood.

1.3.4) HISTORICAL TRENDS IN PLASMA SUPPLY AND DEMAND

The history of the plasma collection industry shows that collection volumes has been cyclical in the past twenty years.

In the early 1980's, a plasma glut caused many small independent plasma centers to close. The fractionators began to build their own centers, becoming less dependent on privately-owned plasma collection facilities. The overall volume of plasma collected increased to meet the growing demand for finished plasma products in Japan. However, in 1986, the self-sufficiency policy of the Japanese Government led to a decline of plasma imports from the U.S. A surplus of plasma soon resulted from this situation, and the price of plasma went down.

During the following years, the demand for cryoprecipitate increased as a result of the lower yield obtained in the production of monoclonal antibody-purified Factor VIII concentrates. This increased the demand for source plasma. Expansion plans were implemented by the plasma collection organizations, and new centers were opened in the late 1980's. At that time, many centers installed plasmapheresis machines, which increased the plasma yield by 10% per donation.

By 1991, the demand for plasma was strong. Through 1993 and 1994, the supply was still tight as a result of the continued demand for plasma derivatives both in the U.S. and abroad. Despite the market penetration of recombinant Factor VIII in the United States, the demand for cryoprecipitate remained at a high level because Aventis Behring (formerly called Armour) and Baxter continued to purchase large quantities of cryoprecipitate to produce Factor VIII concentrate for foreign markets. Also, the demand for IGIV increased, requiring larger volumes of paste II+III. This trend did not seem to abate in 1996, as the prices remained relatively high, and supply was tight. In 1997, the shutdown of the Aventis Behring plant in Kankakee and subsequently the successive shut off of other plant for various periods of time led to a downturn in the plasma demand. The U.S. throughput went down by -17% between 1996 and 1997, and again by -8% between 1997 and 1998, and went up again by 0.4% in 1999.

The use of recombinant Factor VIII did not result in a reduced demand for cryoprecipitate because the overseas markets absorbed the excess plasma-derived clotting factors. By the end of 2001, as virtually all the fractionators were back to full production levels, the demand for source plasma went up again.

In Europe, the risk of CJD deeply affected the plasma markets, and in the UK, the "Cochrane report" on the adverse effects of albumin contributed to a reduced demand for most plasma products, especially albumin. The data on the export of plasma show that the foreign fractionators purchase increased volumes of U.S. plasma, in particular hyperimmune plasma, as their collections of domestic plasma are insufficient to meet the demand for finished products.

1.3.5) PLASMA EXPORT

In 2001, 6.6 million liters of plasma were exported from the United States, a 26.5% increase from 2000. In dollars, the value of the exported plasma went up by 56.0%, due to a higher price per liter, from $80.56 to $99.30 between 2000 and 2001.

The higher demand of U.S. source plasma was attributed to lower blood collections in many countries, and possibly, concerns about BSE transmission. The price of exported plasma increased because of higher production costs.

From 1989 to 1994 US plasma export went down, due to self-sufficiency and a belief that U.S. plasma was less safe than European plasma because it was collected from remunerated donors. This trend reversed itself from 1995 onwards, the demand for U.S. plasma by foreign companies went up again until 1998. In 1999, the volume went down, to go up again from 2000 onward.

The growth in the volume of plasma exported from the U.S. from 1994 was attributed to the insufficient blood collections volumes in several European countries to meet the increased demand for finished products, in particular IGIV.

In 2001, Spain, Switzerland, and Austria and were the three largest importers of U.S. plasma (23.7%, 22.8% and 21.0% respectively). The United Kingdom was fourth with 10.4%. This gradual increase over the past few years reflected the UK health authorities' decision to import plasma from the United States instead of using domestic plasma. In Germany, import of plasma were lower than in previous years (9.9% in 2001), due to increased reliance on plasma generated domestically. For the same reason, Italy decreased its share significantly from 24.7% of the total volume in 1990 to merely 2.7% in 2001.

Japan does not import much source plasma but primarily finished products. In 2001, the export of U.S. plasma to Japan amounted to about 3.3% of the total volume, while it represented 7% of the total volume of exports in 1990. The Japanese Government's self-sufficiency policy was the main reason for this decline.

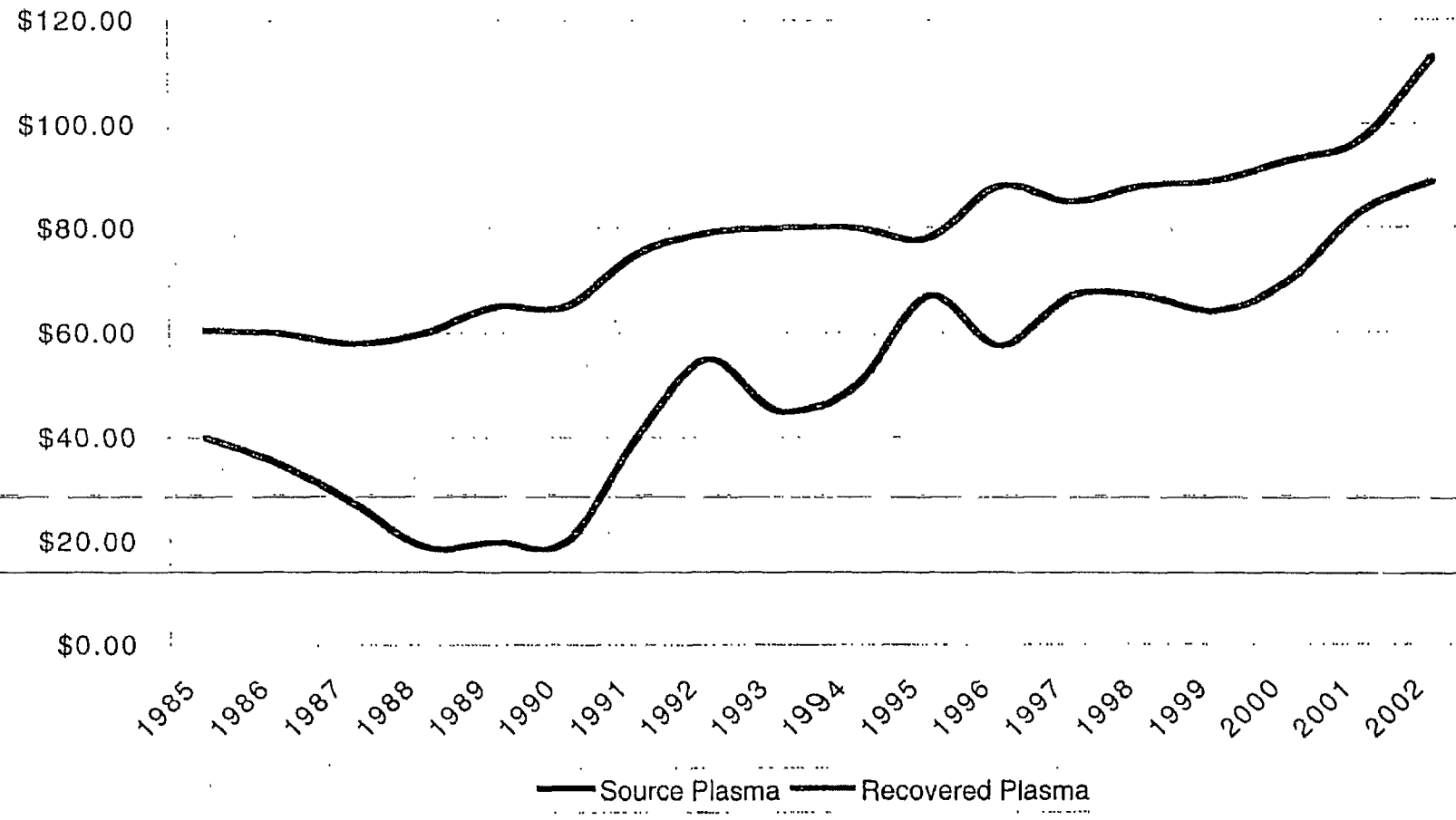
PRICE OF PLASMA IN THE UNITED STATES
(Dollars per Liter)

Year	Source	Recovered
1985	$60.50	$40.00
1986	$60.00	$35.00
1987	$58.00	$27.50
1988	$60.00	$19.00
1989	$65.00	$20.00
1990	$65.00	$20.00
1991	$75.00	$40.00
1992	$79.00	$55.00
1993	$80.00	$45.00
1994	$80.00	$50.00
1995	$78.00	$67.00
1996	$88.00	$57.50
1997	$85.00	$67.00
1998	$88.00	$67.00
1999	$89.00	$64.00
2000	$93.00	$70.00
2001	$97.00	$83.00
2002	$113.00	$89.00

The Marketing Research Bureau, Inc.

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

PRICE OF SOURCE AND RECOVERED PLASMA IN THE UNITED STATES FROM 1985 TO 2002 (Est.)



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THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

Plasma Export from the United States - 2001

	12 months 2001				
	Kilograms	Liters	Dollars	Price/Liter	% Liters
Arab Emirates	12	12	8,100	$655.34	0.0%
Argentina	2,307	2,376	174,109	$73.27	0.0%
Australia	15,678	16,148	1,443,892	$89.41	0.2%
Austria	1,342,826	1,383,111	129,301,701	$93.49	21.0%
Belgium	6,957	7,166	835,772	$116.63	0.1%
Brazil	906	933	455,689	$488.32	0.0%
Canada	11,391	11,733	5,625,163	$479.44	0.2%
Chile	41	42	9,389	$222.33	0.0%
China (Taiwan)	21	22	4,500	$208.04	0.0%
Cyprus	78	80	2,698	$33.58	0.0%
Czech Republic	469	483	45,290	$93.75	0.0%
Denmark	5,120	5,274	484,161	$91.81	0.1%
Finland	220	227	56,916	$251.17	0.0%
France	79,631	82,020	18,528,122	$225.90	1.2%
Germany	634,360	653,391	95,243,232	$145.77	9.9%
Greece	16	16	17,399	$1,055.76	0.0%
Hong Kong	119	123	51,601	$420.99	0.0%
Hungary	17	18	6,661	$380.41	0.0%
India	44	45	10,917	$240.89	0.0%
Ireland	1,727	1,779	286,194	$160.89	0.0%
Israel	30,798	31,722	2,729,406	$86.04	0.5%
Italy	134,721	138,763	15,919,767	$114.73	2.1%
Japan	208,428	214,681	20,234,755	$94.26	3.3%
Kenya	27	28	3,200	$115.07	0.0%
Korea (Rep)	184,881	190,427	30,127,014	$158.21	2.9%
Kuwait	476	490	34,618	$70.61	0.0%
Mexico	9,352	9,633	1,207,637	$125.37	0.1%
The Netherlands	5,233	5,390	256,047	$47.50	0.1%
New Zealand	91	94	10,161	$108.41	0.0%
Norway	206	212	59,205	$279.03	0.0%
Panama	36	37	5,604	$151.13	0.0%
Portugal	77	79	7,218	$91.01	0.0%
Russia	96	99	16,433	$166.19	0.0%
Saudi Arabia	334	344	30,143	$87.62	0.0%
Singapore	10,013	10,313	683,224	$66.25	0.2%
South Africa	30	31	2,625	$84.95	0.0%
Spain	1,511,734	1,557,086	165,883,205	$106.53	23.7%
Sweden	63,997	65,917	6,266,378	$95.06	1.0%
Switzerland	1,457,246	1,500,963	95,402,333	$63.56	22.8%
Taiwan	92	95	21,811	$230.17	0.0%
Tanzania	2	2	6,992	$3,394.17	0.0%
Thailand	15	15	16,313	$1,055.86	0.0%
Turkey	67	69	92,353	$1,338.26	0.0%
United Kingdom	664,726	684,668	61,404,068	$89.68	10.4%
Uruguay	102	105	16,616	$158.16	0.0%
Venezuela	487	502	21,900	$43.66	0.0%
Others	0	0	21,900	N.A.	0.0%
TOTAL	6,385,207	6,576,763	653,050,532	$99.30	100.0%

Source: US Government Trade Data/Marketing Research Bureau
Assumption: one liter of plasma weights 937 grams

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

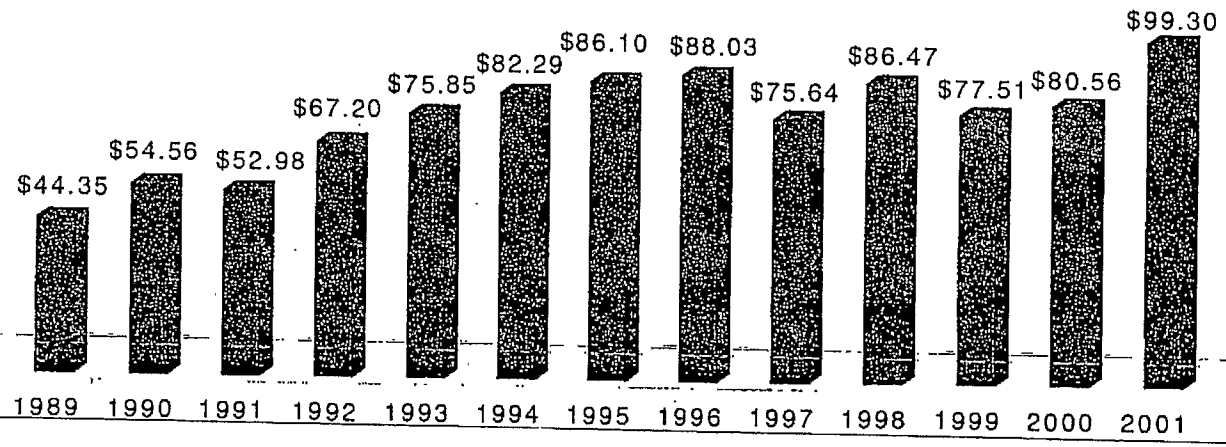
Export of Source and Recovered Plasma from the United States From 1989 to 2001 (Liters, dollars, Percent Change and Price per Liter)

Year	Liters	Value ($)	Chge/Liters	Chge/Value	$/liter
2001	6,576,763	653,050,532	26.5%	56.0%	$99.30
2000	5,197,862	418,753,353	12.4%	16.8%	$80.56
1999	4,623,993	358,416,563	-9.2%	-18.6%	$77.51
1998	5,092,070	440,287,653	3.2%	18.0%	$86.47
1997	4,933,915	373,196,604	14.1%	-2.0%	$75.64
1996	4,324,191	380,646,681	15.5%	18.1%	$88.03
1995	3,744,005	322,370,165	24.8%	30.5%	$86.10
1994	3,000,746	246,941,613	-9.2%	-1.5%	$82.29
1993	3,303,929	250,599,121	-1.6%	11.1%	$75.85
1992	3,357,778	225,632,096	-20.8%	0.4%	$67.20
1991	4,240,250	224,665,024	-6.2%	-8.9%	$52.98
1990	4,519,781	246,583,946	-5.7%	16.0%	$54.56
1989	4,793,140	212,560,886			$44.35

Source: US Government Trade Data/Marketing Research Bureau

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

AVERAGE PRICE PER LITER OF PLASMA EXPORTED FROM THE UNITED STATES FROM 1989 TO 2001



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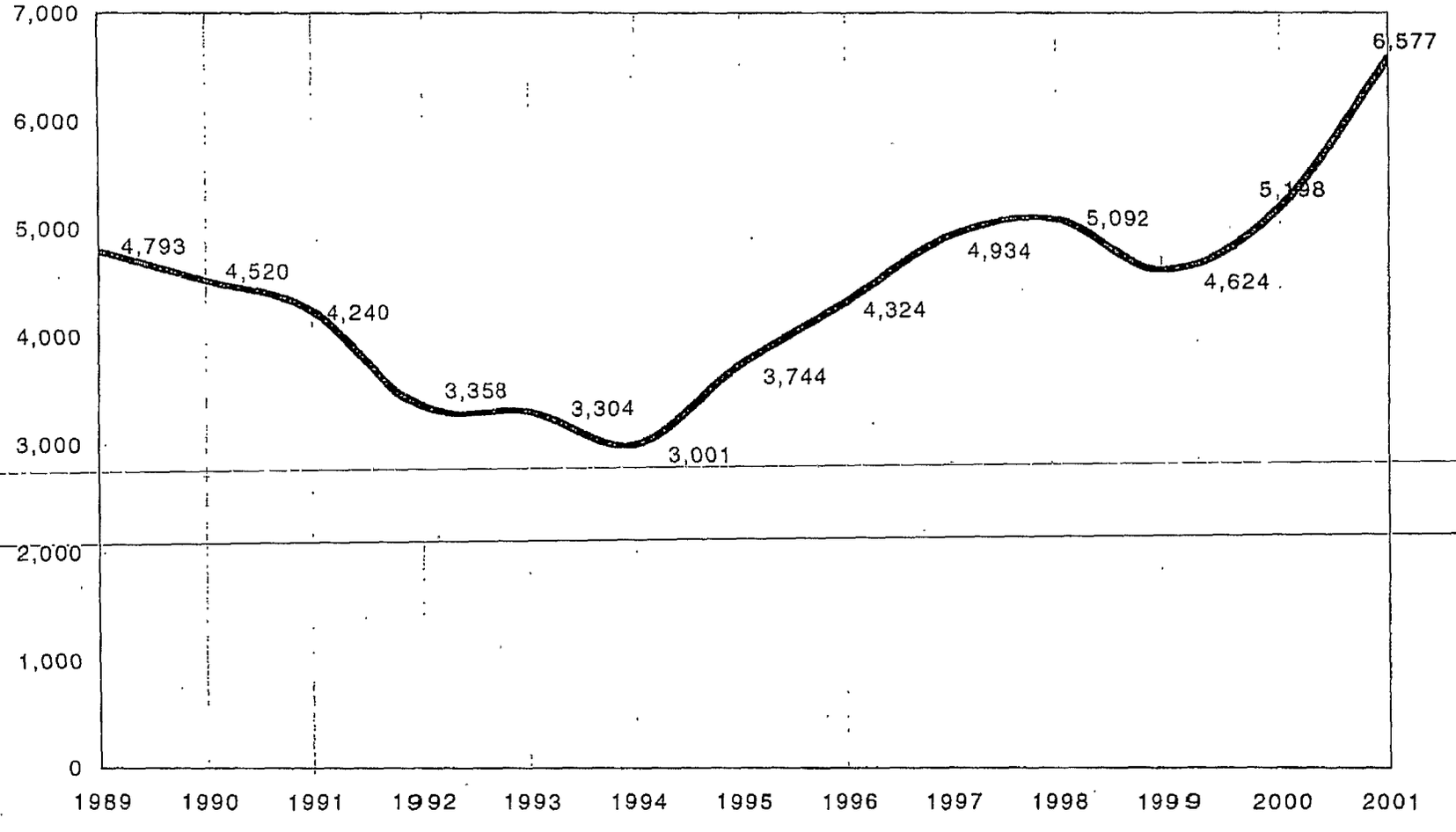
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

EXPORT OF PLASMA FROM THE UNITED STATES (SOURCE & RECOVERED) FROM 1989 TO 2001

Liters X 1,000



37

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1.3.6) PLASMA PRICES

Historical Development

In 1985, the price of source plasma in the U.S. ranged between $58 and $63 per liter. The price of recovered plasma declined from $57 per liter to $40, because the demand for this type of plasma was limited.

By the end of 1987, the price of recovered plasma was $25-30 per liter. Contracts for source plasma were still negotiated at about $58 per liter, and spot prices were 10% higher. By the end of 1988, prices per liter for source plasma from independent contract centers amounted to about $60 per liter, fresh frozen plasma was sold for $40 per liter, and the price of recovered liquid plasma was under $20.

At the end of 1989, the prices of plasma in the United States was approximately $62 per liter for and $67 for European customers. Spot prices without testing reached $70. Outdated liquid plasma was used primarily for diagnostics, and was sold for $20 per liter.

By 1990, the additional plasma available from new collection centers pulled the prices down but higher costs triggered by automation and donor testing pulled them up. As a result, no significant changes in pricing occurred during that year.

In 1991, many source plasma centers had begun HCV and HIV-2 testing in order to meet the European requirements for plasma and for plasma products beginning in 1993. Most were attempting to add $10 per liter to compensate for the new testing and the increased rate of donor rejections. The short-term albumin demand from the Gulf War resulted in a resurgence in demand for recovered liquid plasma, which was sold for $40 per liter. Donors were paid an average of $15 for each donation.

By the end of 1992, plasma supplies were reportedly tight as most major fractionators were looking for plasma. Prices averaged $75 per liter for source plasma for domestic and $82-$84 for export. The market for frozen plasma recovered from whole blood rebounded to $55 per liter. Specialty plasmas were also in great demand and at high

prices. This trend continued through 1993. Domestic source plasma reached $80 per liter. In 1994, the average selling price for large contracts was in the $78 to $82 range depending on the volume and delivery date. Recovered plasma averaged $45 per liter but could sell for as much as $70 to diagnostic manufacturers.

In early 1996, the price of source plasma was about $80 to $81 per liter for new contracts. The new antigen test added about $5 to $15 to the price of one liter of plasma. This included the cost of the test, of the technician's time, and of logistics (each liter of plasma has to be accompanied with a frozen sample). In the same way as the introduction of the HCV test led to increased rejection rates, some donations were rejected because of the false positives with the p24 test. By the end of the year, the price of source plasma reached $88 per liter, higher (up to $115/liter) on the spot market and/or for small quantities.

By the fall of 1997, the price of plasma under current contracts was about $83 while new contracts were signed for $84-$86 per liter. The price increase was attributed to the requirement from customers to buy only plasma, which had been PCR-tested and quarantined for three to six months. The cost of keeping one liter of plasma on inventory was estimated at $0.25 per liter per month. A four months quarantine therefore increased the price of plasma by $1.00, six months by $1.50, and so on.

Source Plasma

Through 2001, the price of source plasma was about $97 per liter, going above the $100 mark in 2002. The NAT testing – made by the fractionators, and therefore not affecting the price from the collection centers - added some $10 to $15 to the price.

Plasma donors centers have been relocating to new and more attractive sites, and this has contributed to changing the profile of plasma donors. They are no longer unemployed, undocumented alien, or transient individuals in need of quick cash. Today's plasma donor population comprises students, housewives, and persons with steady employment

who use plasma donation as a way to get some extra cash for items of secondary necessity. For this reason, they do not give plasma twice a week, as did those for whom plasma donation was vital, and the frequency of the donation is lower than previously. This contributes to increasing the donor recruitment expenses because more donors are needed to generate the same volume of plasma. Furthermore, the incentives paid by the plasma centers have been raised in order to retain donors.

In mid-2001, the price of source plasma was reported to be about $97 per liter (not NAT-tested), and to $108 to $118 by mid-2002. The price of source plasma is expected to continue to climb – possibly reaching over $120 per liter in early 2003 -, due to the following factors:

- High donor recruitment costs and screening, including the effect of new FDA regulations on donor selection, (exclusion of blood and plasma donors who spent some time in Europe),
- Higher demand for finished plasma products, as the fractionators increase their throughput,
- Increased demand from foreign customers, and

Anti-D Plasma

Most contracts involve plasma with a titer of 25 to 35 micrograms per mL. In mid 2002, the price was about $450 for 25 to 35 mcg/mL. In mid-2001, the price was estimated at $525 per liter. The price of anti D plasma went down because of an oversupply resulting from:

1) Precautionary inventory built up by some fractionators in recent years,
2) Lower production of Rh immune globulin resulting from plant slow-down or shut-down in 1998/99 (reportedly Aventis Behring in Marburg, and Pharmacia & Upjohn in Stockholm), and
3) Higher domestic production of anti D plasma by the non-profit blood transfusion services, allowing them to diminish their reliance on imported anti D plasma.

In 1994, Anti-D plasma was sold for about $350 to $400 per liter (30 mcg/mL). In 1995, Anti-D plasma with a titer of 33 to 35 mcg/mL was sold for at least $450 per liter, and over $375 for a lower titer (20 mcg/mL). The price continued to go up to reach $500 per liter by yearend.

By 1996, the price reached $450 to $500 per liter (20 mcg/mL). For a titer ranging from 30 to 40 mcg/mL, the price ranged from $500 to $600 per liter.

In 1997, the price of anti D plasma continued to go up: from $500 to $600 for 20 mcg/ml, $600 and up for 30 mcg/ml per liter. Anti D plasma with higher titers (40 mcg/mL and more) was generally unavailable.

By 1998, the price of anti D plasma was estimated at $575 to $650 per liter (25 mcg/ml), not much different from 1997. But then it went down in 1999, reaching approximately $525 per liter for 25-35 mcg/ml

The worldwide production of anti D plasma is estimated at about 500,000 liters per year.

Anti-Cytomegalovirus and Varicella Zoster Plasma

The price may vary significantly, depending on the titer requirements set by customers. The donors are not boosted with a vaccine, as in the case of hepatitis B or Anti D, but the titer may vary substantially from one donor to another. In 2002, as in 2001, the price of these two types of plasmas ranged from $130 to $140 per liter. In early 2000, it was reported to be between $115 and $135 per liter. In 1999, the price of CMV plasma averaged $110 per liter. In 1998, the price of anti Varicella Zoster Plasma ranged from $95 to $100 per liter.

In 1994 and 1995, the average price of CMV-high titer plasma did not exceed $100 per liter. In early 1996, CMV plasma cost $92-118 per liter depending on the type of contract, payment conditions, volume ordered and quality. By mid-1996, the cost went up to $100-$115 per liter and remained at the same level through 1997. In some cases, the

price could reach up to $160 per liter for high quality and high titer product.

Anti-Tetanus Plasma

In 1999, the price of anti-Tetanus plasma began to climb because of the unavailability of tetanus toxoid vaccine. In mid-2002, the price of Tetanus plasma was $125 to $150 per liter for the standard titer of 15 IUs per ml. In 2001, it was $125 per liter, and in early 2000, $115 per liter, up $10 to $20 from the previous year ($93-105 per liter).

In the absence of the high quality toxoid from Berna, Switzerland, donors are vaccinated with vaccines made by other manufacturers, such as SmithKline Beecham, Lederle and Connaught. While they offer excellent protection against the disease, they generate a lower titer in the donor plasma than Berna's vaccine. Therefore, a larger number of donors must be vaccinated in order to secure the same volume of anti-Tetanus plasma as before, contributing to an increase in cost.

Anti-Rabies Plasma

In mid-2002, the price of anti-Rabies plasma was estimated at $250 per liter, remaining within last year's range from $235 to $290 per liter. For several years, the price of this type of plasma has remained relatively stable. The number of customers is limited, too, and no real competition exists to bring prices up or down. If the plasma titer is not ascertained, this plasma can fetch a price of only $130 per liter.

Anti-Hepatitis B Plasma

In 2002, the price of hepatitis B plasma continued to go up. In mid-2002, it was estimated at $575 per liter for 40 IU/mL, a slight increment from the previous year. In mid-2001, the price per liter of anti-hepatitis B plasma was $450 (20 IUs/mL), $475 (30 IUs/mL), and $525 (40 IUs/mL).

In 1999, the price per liter (40 IUs/liter) of anti-hepatitis B plasma was reported to be in the $450 to $475 range.

In 1996, the price was about $550 per liter with a titer of 50-75 International Units per mL. In 1997, the price was as follows:

- With a titer of 60 IUs per mL: $650-$675 per liter
- With a titer of 40 IUs per mL: $450 per liter
- With a titer of 20 IUs per mL: $250-$300 per liter

Anti-Pseudomonas and Anti-Respiratory Syncytial Virus (RSV) Plasma

Only small quantities of these types of plasma are collected, there is therefore no "market" price for them.

Recovered and Liquid plasma

In mid-2002, the price of recovered plasma ranged between $86 and $92 per liter, a substantial increase from the previous year, when it was $80 to $83 per liter, and $65 to $75 per liter in the prior year.

In 1998, the price paid to the US blood banks for one liter of fresh plasma frozen within 24 hours was about $63, unchanged from 1997. It was lower than the $65 to $70 per liter paid a year before, due to the perceived risk of CJD transmission and resulting in lower demand.

In 2002, the price of liquid plasma was about $60 per liter, depending on the quality of the product and contractual agreements, virtually unchanged from 1998.

Plasma for diagnostic use is sold for approximately $30 to $35 per liter.

2) PLASMA FRACTIONATION

2.1) PROCESSING CAPACITY AND THROUGHPUT

In 2001, it was estimated that the plasma throughput of the U.S. plasma fractionators was about 6.3 million liters, about 8% higher than in 2001, as all the fractionators had resumed full production levels.

The following table summarizes the estimated fractionation capacity in 2001 of the U.S. fractionators. Only one non-profit fractionator operates in the United States (Massachusetts Biologic Laboratory) after the Michigan Biologic Products Institute was privatized in 1998, and acquired by "Bioport Corporation", which shut it down in 2000.

Estimated Plant Fractionation Capacity & Throughput
In Thousand Liters per Year - 2001

Company	Estimated Capacity	Estimated Throughput
Alpha Therapeutic	2,000	650
Baxter Bioscience (include. ARC)	2,500	2,010
Bayer	2,250	1,950
Aventis Behring (U.S. only)	2,250	1,250
Massachusetts Biologic Laboratory *	250	50
Ortho Clinical Diagnostics	42	25
Vitex (V.I. Technologies)	800	600
Total Capacity	10,837	6,535

* Not-for-profit

It can take up to seven months from the time plasma is collected until the final product is released, as shown below:

- Collection of the plasma and testing (10 days),
- Inventory hold (60 days),
- Staging and internal quality control (10 days),
- Plasma pooling (1 to 2 days),
- Fractionation (7 to 10 days),

- Collection of intermediates and runs for internal quality control (20 days),
- Preparation of the final products (7 to 10 days),
- Quality control prior to filling of final products (25 to 28 days),
- Manufacture of final products, FDA testing and release (60 days). This last step has recently been reduced to two weeks or less for most products.

By the end of 2001, the corrections required from the fractionators as a result of the FDA observations in previous years were largely completed, and most fractionators were back in operation: Aventis Behring, Bayer and Baxter operated at near full capacity, while Alpha Therapeutic resumed full operations in the beginning of August 2001. In a 2002 presentation entitled "Ten years after... What has been achieved by Consent Decrees", an FDA official summarized the record of the regulatory actions and industry compliance since 1996:

	1996	***1997***	***1998***	***1999***	***2000***	***2001***
Source plasma inspections						
"Classifications"	14	11	33	10	12	13
Compliance rate	96%	96%	90%	96%	95%	95%
Plasma derivatives						
inspections (enforcement)	-	30(12)	28(4)	29(2)	16(2)	17(4)
Derivatives compliance rate	-	60%	86%	93%	92%	85%
Warning letters – blood and source plasma	11	10	5	3	2	1

The FDA concluded that (1) the blood supply is safer than ever, (2) there is increased CGMP awareness and compliance, and (3) injunctions protect the consumer from unapproved or potentially dangerous products.

In 2000, the Plasma Protein Therapeutics Association (PPTA) launched "QSEAL" (Quality Standards of Excellence and Leadership), a quality certification program for all fractionators worldwide. The program

provides an independent evaluation and certification recognizing a fractionator's adherence to PPTA's standards. Most U.S. fractionators are QSEAL-certified.

2.2) PLANT EXPANSIONS

In the past few years, most U.S. fractionators have invested in plant renovation, improvement and expansion, in part due to the need to comply with GMPs and FDA-mandated changes and to increase production capacity and, in most cases, production yields. In this respect, the need to supply more IGIV to the U.S. market in 1997/98 was a strong motive for such improvements as well.

Following the Consent Decree and plant shut down of its plant in Los Angeles, Alpha Therapeutic has made numerous improvements to its manufacturing facility. Using funds from the parent company, Welfide, the production facility for IVIG was enhanced in 1999 and 2000. Furthermore, the company added 80,00 square feet to the plant to include new aseptic filling lines and other improvements. However, its overall processing capacity remained unchanged at close to two million liters of plasma.

Bayer operates a fractionation facility in Clayton, North Carolina, where the Canadian Red Cross plasma is fractionated under contract (approximately 150,000 liters per year). In 2002, the fractionation contract was renewed for a period of two years, renewable. Bayer has an agreement with Precision Pharma in Melville, New York for the processing of plasma or intermediate bulk products. Recently, Bayer built a new production facility in Clayton for the production of its new chromatography-purified, double virus inactivated liquid IVIG to be introduced in the near future as the successor of "Gamimune-N". Bayer's old fractionation facility in Berkeley, California is only used to process intermediate paste for the production of Alpha-1 Antitrypsin and Antithrombin III.

Baxter's (formerly Hyland) plant in Glendale, California has over two million liters capacity. Half of its capacity is allocated to the American Red Cross, in accordance with an agreement to be renewed in

2005. As this plant was originally build in the 1950's, in 1999, Baxter announced plans to upgrade it, and in 2000, to build another one adjacent to it. The new plant will have 40,000 square feet and essentially replace the old one, without increasing the overall fractionation capacity. The new plant will be operational in 2003. Furthermore, Baxter operates the former Immuno facility in Michigan as a result of the acquisition of this facility in 1997. Substantial improvements have also been made at the Rochester plant.

Plant expansion have been noted only at Precision Pharmaceuticals in Melville, NY (formerly Vitex) which increased its fractionation capacity from 660,000 liters to 800,000 liters.

2.3) PRODUCTION YIELDS

Polyvalent Intravenous Immune Globulin (IGIV)

At least four grams per liter is now the generally accepted estimate for the yield of IVIG. The not-for-profit fractionators generally have a higher yield than the commercial sector because recovered plasma has more protein than source plasma. The chromatography process implemented by various companies, in partiuclar Bayer, has contributed to the yield improvement.

Polyvalent Intramuscular Immune Globulin (IGIM)

Same yield as IGIV.

RhoD Immune Globulin

There are between 20 and 40 micrograms (mcg) of Anti-D antibodies in one ml of hyperimmune Anti-D plasma, or 20,000 mcg to 40,000 mcg in one liter of plasma. The manufacturing process of RhoD immune globulin reduces the RhoD activity by some 70%. Therefore, after processing, one liter of plasma contains in production has only 6,000 to 12,000 mcg, from which some 19 to 38 vials of finished product (320 mcg per vial) can be made. Cangene reportedly has the industry's highest yield because it uses a chromatography process.

Tetanus Immune Globulin (TIG)

Human plasma contains 17 IUs of tetanus immune globulin per milliliter. One liter has therefore 17,000 IUs of TIG. The fractionation process takes out 55% of the protein, leaving 45% in the final vial, or 7,650 IUs. Since a vial usually contains 250 IUs, one liter of plasma allows the production of approximately 30 vials of finished product.

Albumin/Plasma Protein Fraction (PPF)

One liter of plasma typically contains 53 grams of proteins (53% of protein/liter). 55% of it, or 29 grams, is albumin. The fractionation process loses about 15% of the proteins, so 25 grams are left. This is the average yield normally obtained industry-wide. The yield obtained by the not-for-profit companies is higher than the yield obtained by the commercial firms because the plasma of volunteer donors contains more proteins.

Factor VIII Concentrate

Monoclonal-antibody purified: 120 to 150 international units per liter of FFP. Intermediate-purity: 280 IUs. A liter of fresh frozen plasma has about 7,000 IUs and the yield is 20%.

Factor IX Concentrate

It is generally estimated that the yield is 250 to 450 IUs per liter of plasma. The monoclonal-purified product has a lower yield, the ratio to the standard product being possibly comparable to the yield of Factor VIII.

Antithrombin III

One liter of plasma contains about 900 IUs of Antithrombin III. The fractionation process loses about 55%, leaving some 400 to 480 IUs after fractionation.

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES

SALES BY PRODUCTS (PLASMA PRODUCTS ONLY) IN $(000)

	1980	1988	1988	1990	1992	1994	1996	1997	1998	1999	2000	2001
POLYV. INTRAMUSC. IGG	3.8	3.4	3.0	3.5	4.3	4.3	4.8	2.4	8.5	6.7	4.1	2.8
POLYV. IGIV	-	49.9	122.9	190.1	235.5	349.6	427.5	437.7	559.0	755.0	837.3	1,041.9
HYPERIMMUNE GLOBULINS	20.7	32.5	35.2	33.6	41.5	62.6	122.1	210.0	225.7	239.5	660.7	227.6
RHOD	12.0	17.8	17.5	17.0	18.1	18.5	30.2	72.4	87.0	104.0	99.6	74.7
TETANUS	2.7	2.2	2.2	2.2	3.8	4.0	1.3	4.7	7.0	4.9	3.5	5.4
HEPATITIS B	4.2	8.9	9.0	8.7	7.2	10.2	22.7	29.0	36.1	41.0	40.0	37.8
RABIES	1.7	3.6	5.5	5.8	8.0	8.0	27.6	31.3	43.2	44.8	46.3	41.5
ALL OTHERS	0.1	-	1.0	1.9	6.4	21.9	40.4	72.6	52.2	44.8	471.3	68.2
ALBUMIN	131.0	171.9	135.7	194.2	281.0	300.2	331.1	317.0	395.2	271.6	217.7	232.3
PPF	40.6	42.7	28.9	37.7	49.3	51.5	37.2	29.3	3.8	-	-	-
FACTOR VIII	42.0	54.8	170.9	248.5	256.6	223.9	165.6	143.4	129.9	170.7	688.3	202.5
FACTOR IX	10.8	12.4	13.4	10.0	30.2	77.9	93.9	62.2	39.1	28.4	171.3	49.7
ACT. FIX COMPLEX	0.3	17.6	15.0	17.8	25.8	40.2	45.7	47.8	58.9	61.6	162.2	250.3
ALPHA 1 ANTITRYPSIN	-	-	5.0	15.2	29.4	44.4	52.2	55.0	60.2	54.4	107.6	89.1
AT III	-	-	-	-	2.7	7.5	10.1	10.2	12.0	9.4	5.0	2.7
FIBRIN GLUE	-	-	-	-	-	-	-	-	3.0	36.1	41.4	42.9
TOTAL MARKET ($ MILLIONS)	$249.2	$385.2	$530.0	$750.8	$956.3	$1,162.1	$1,310.2	$1,314.9	$1,495.2	$1,633.8	$2,915.6	$2,033.6
GROWTH RATE (%)					+ 27%	+ 22%	+ 7.1%	+0.4%	+7.3%	+13.7%	+13.4%	+17.4%

SOURCE: THE MARKETING RESEARCH BUREAU, INC.

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

THE US PLASMA FRACTIONS MARKET - 2001
WITHOUT RECOMBINANT FACTORS

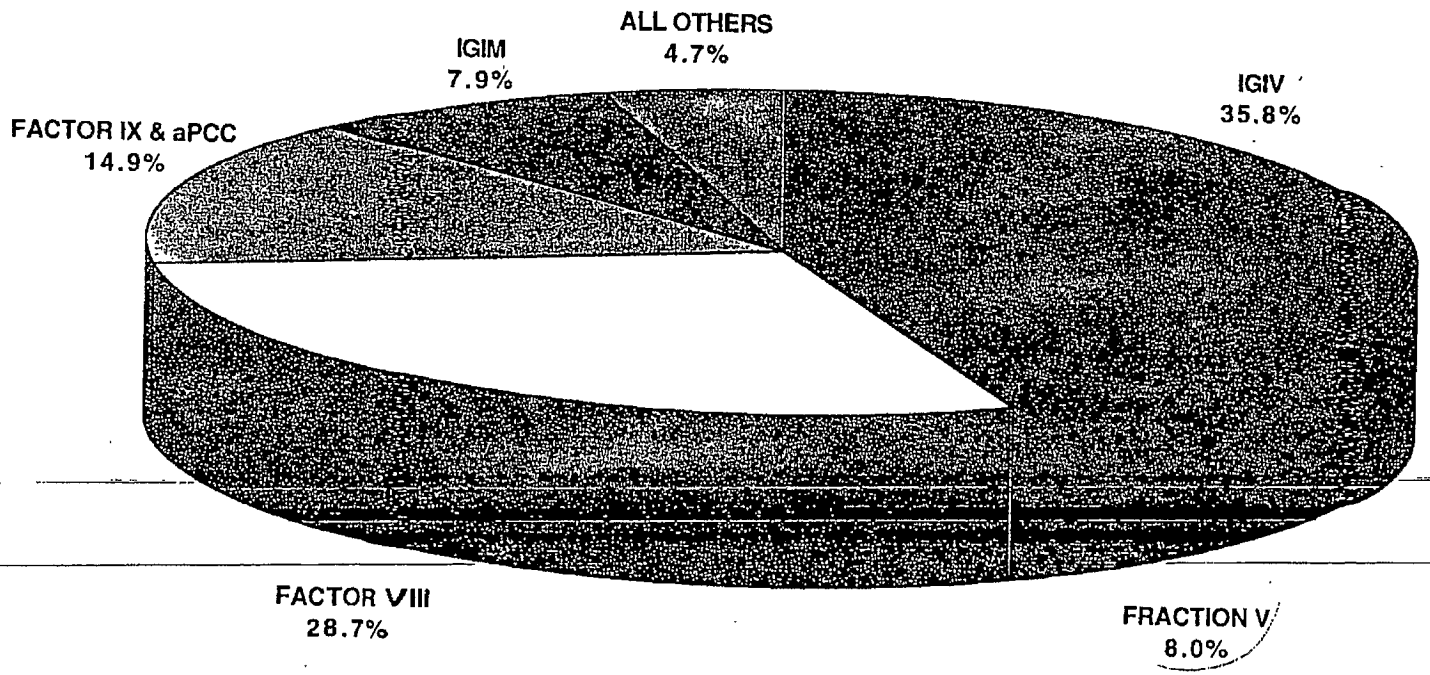
COMPANY	DOLLARS (MM)	MARKET SHARE	CHANGE 01/00
Bayer	336.621	16.6%	-10.5%
Bioport	0.200	0.0%	-99.8%
Alpha Therapeutic	130.218	6.4%	225.9%
Novartis	29.400	1.4%	-3.6%
Aventis Behring	345.300	17.0%	16.4%
Baxter	466.578	22.9%	23.8%
Ortho Clinical Diagnostics	61.200	3.0%	15.0%
American Red Cross	378.830	18.6%	30.0%
Aventis Pasteur	30.000	1.5%	-14.5%
Nabi	73.060	3.6%	3.5%
Haemacure	11.640	0.6%	-6.8%
Genetics Institute	0.000	0.0%	N.A.
Massachusetts Laboratory	3.958	0.2%	-61.6%
Novo Nordisk	0.000	0.0%	N.A.
MedImmune	33.200	1.6%	-13.2%
ZLB Bioplasma	133.418	6.6%	422.2%
Total	2,033.621	100.0%	17.4%

THE US PLASMA FRACTIONS MARKET - 2001
INCLUDING RECOMBINANT FACTORS

COMPANY	DOLLARS (MM)	MARKET SHARE	CHANGE 01/00
Bayer	370.821	12.7%	-17.6%
Bioport	0.200	0.0%	-99.8%
Alpha Therapeutic	130.218	4.5%	225.9%
Novartis	29.400	1.0%	-92.4%
Aventis Behring	392.050	13.5%	2.0%
Baxter	905.778	31.1%	27.0%
Ortho Clinical Diagnostics	61.200	2.1%	15.0%
American Red Cross	378.830	13.0%	30.0%
Aventis Pasteur	30.000	1.0%	-14.5%
Nabi	73.060	2.5%	3.5%
Haemacure	11.640	0.4%	-6.8%
Wyeth	165.200	5.7%	16.5%
Massachusetts Laboratory	3.958	0.1%	-61.6%
Novo Nordisk	190.000	6.5%	55.1%
MedImmune	33.200	1.1%	-92.9%
ZLB Bioplasma	133.418	4.6%	422.2%
Total	2,908.971	100.0%	-0.4%

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

Product Mix with Recombinant Factors VIII, IX and VII:a
(Market Shares based on Sales in Dollars)

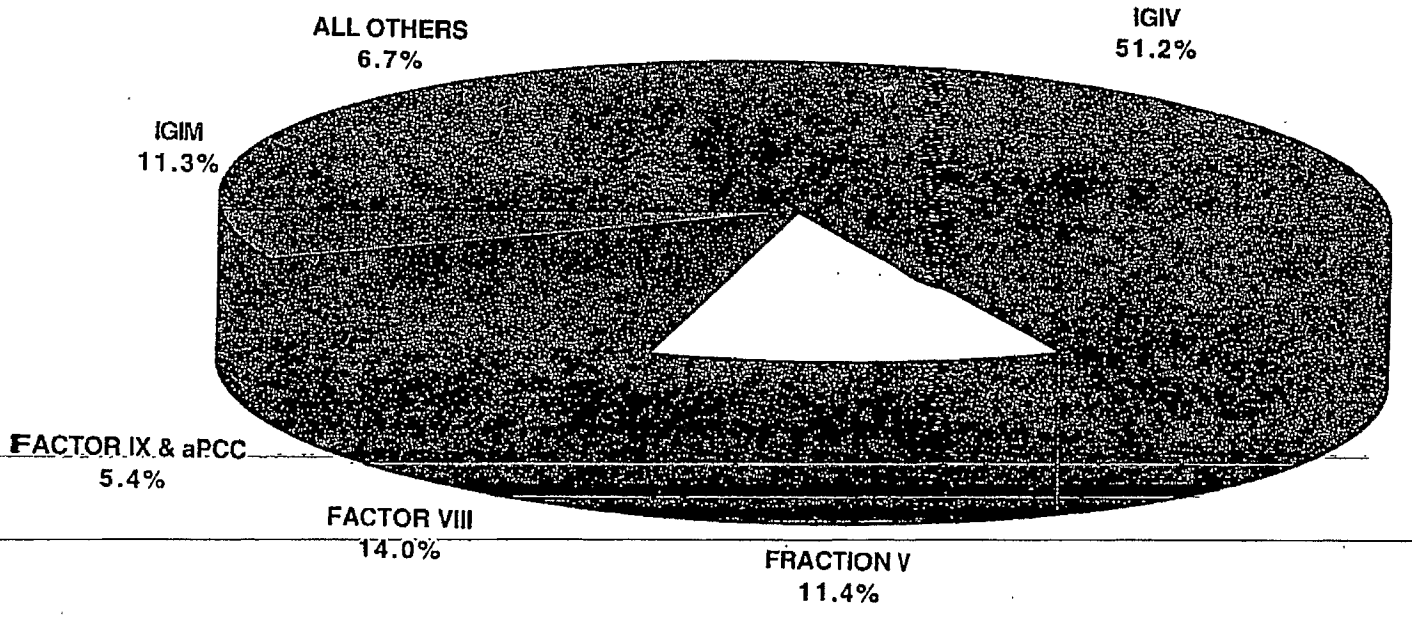


Total Market: $2,908.9 Million

The Marketing Research Bureau, Inc.

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

Product Mix without Recombinant Factors VIII & IX, & VII:a
(Market Shares based on Sales in Dollars)



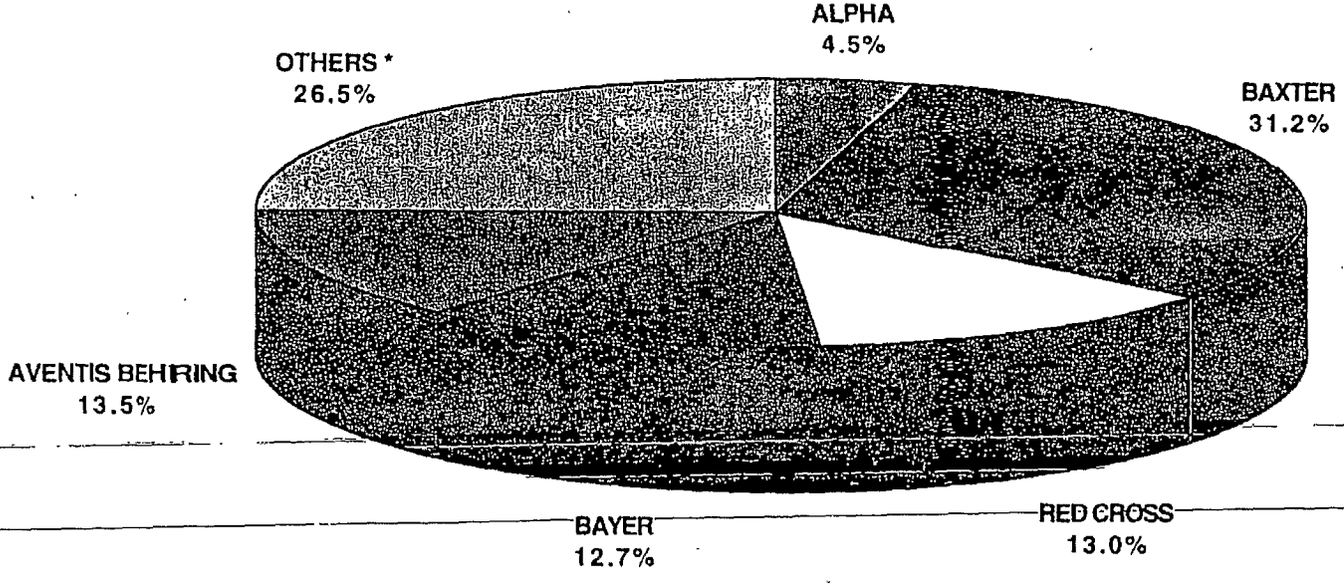
Total Market: $2,033.6 Million

The Marketing Research Bureau, Inc.

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

MARKET SHARES BY COMPANY
With recombinant Factors

~~Total Market: 2,908.9 Million~~



* Includes Bioport, NABI, Novartis, Ortho, ZLB, Mass Biol. Lab., etc.

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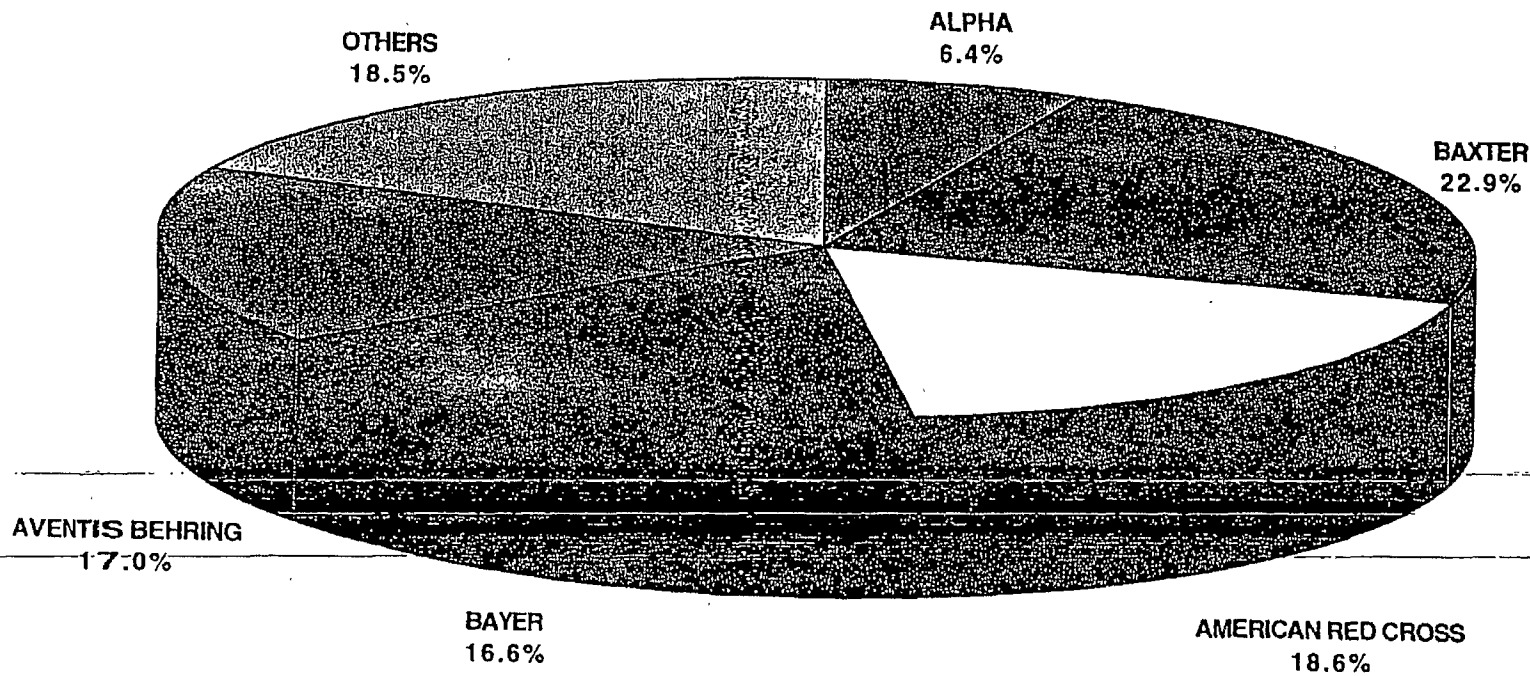
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

MARKET SHARES BY COMPANY
Without recombinant Factors

TOTAL MARKET: $2,033.6 MILLION



* Includes Bioport, Nabi, Novartis, Ortho, ZLB, Mass Biol. Lab., etc.

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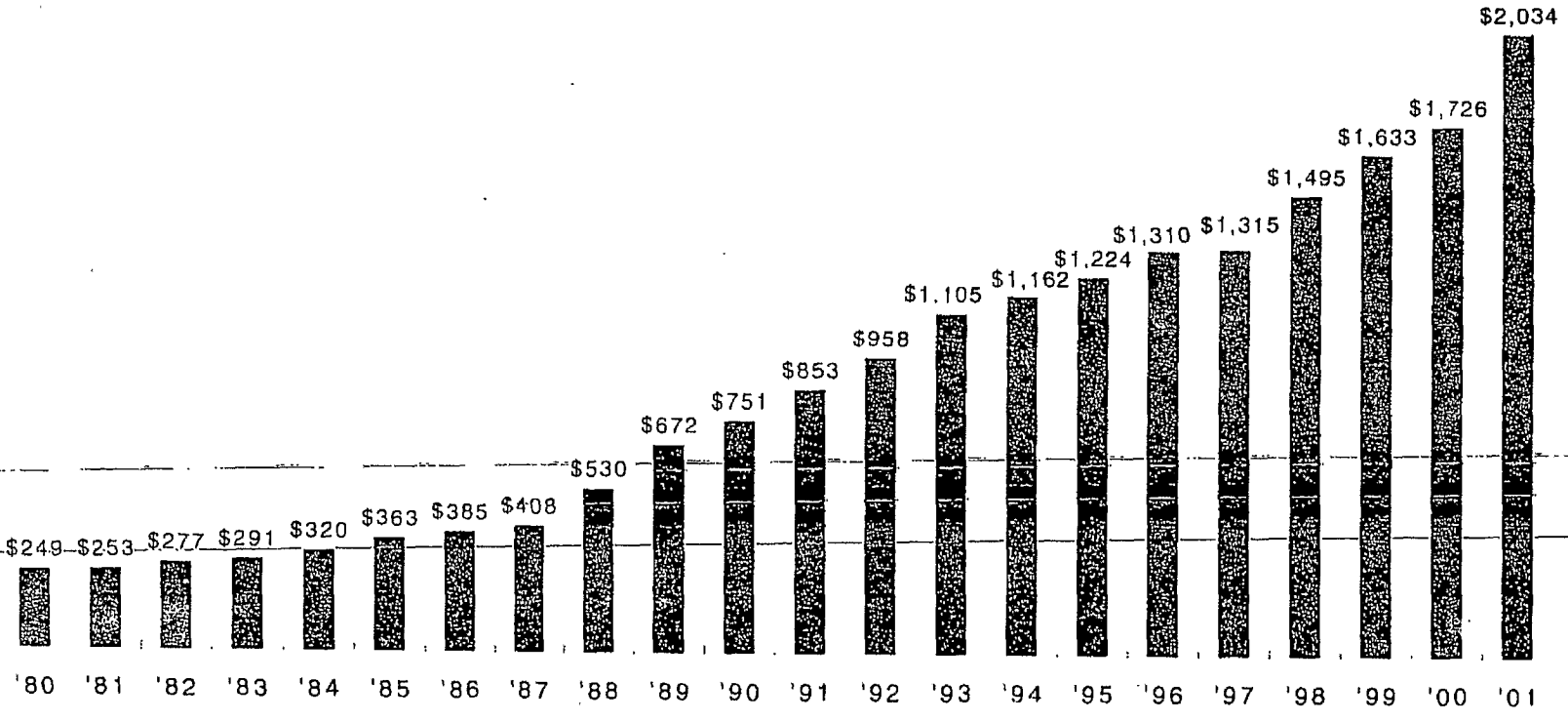
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

TOTAL MARKET FROM 1980 TO 2001 IN DOLLARS

Without rFVIII, rFIX, and rFVII:a ($000)



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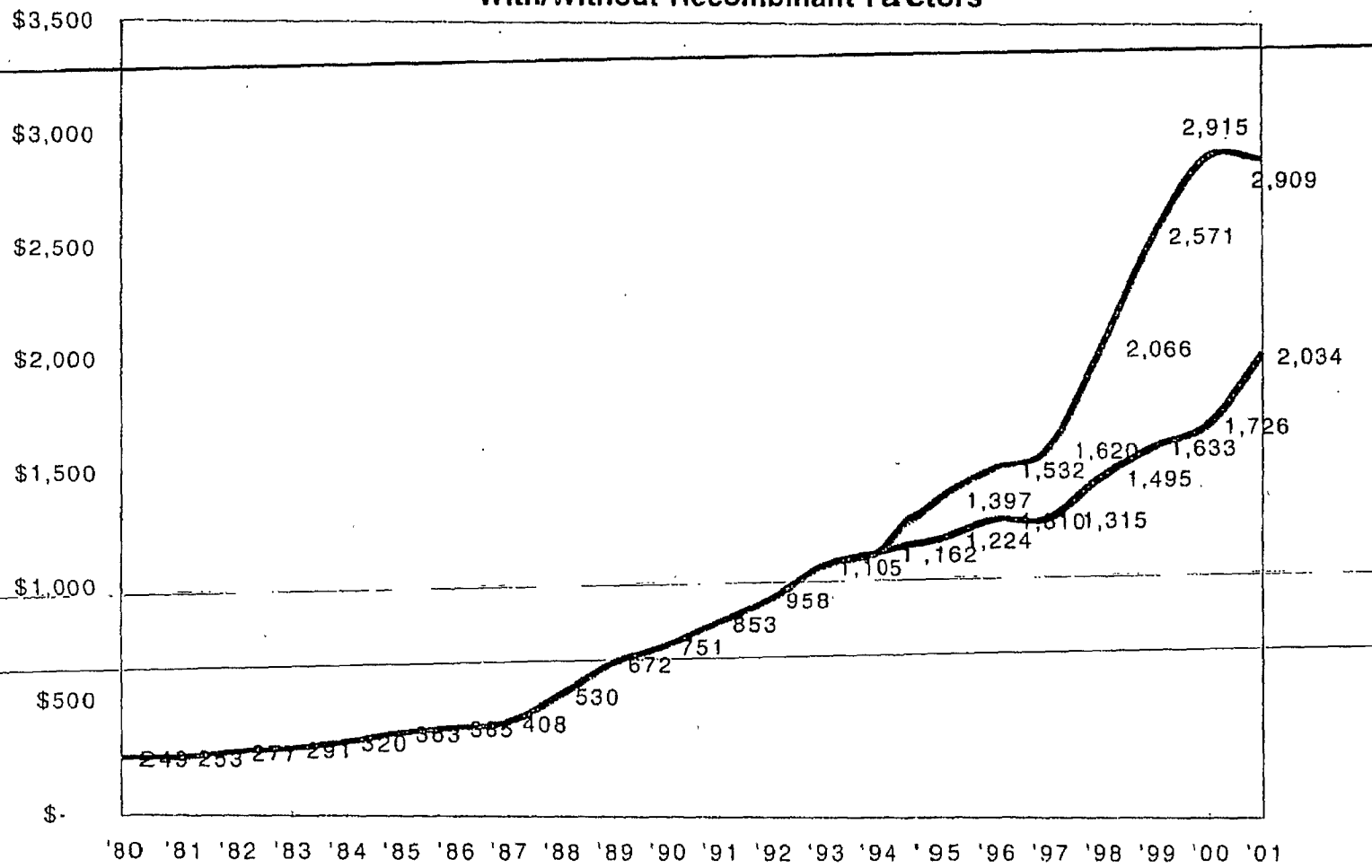
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

TOTAL MARKET
From 1980 to 2001 ($000)
With/Without Recombinant Factors



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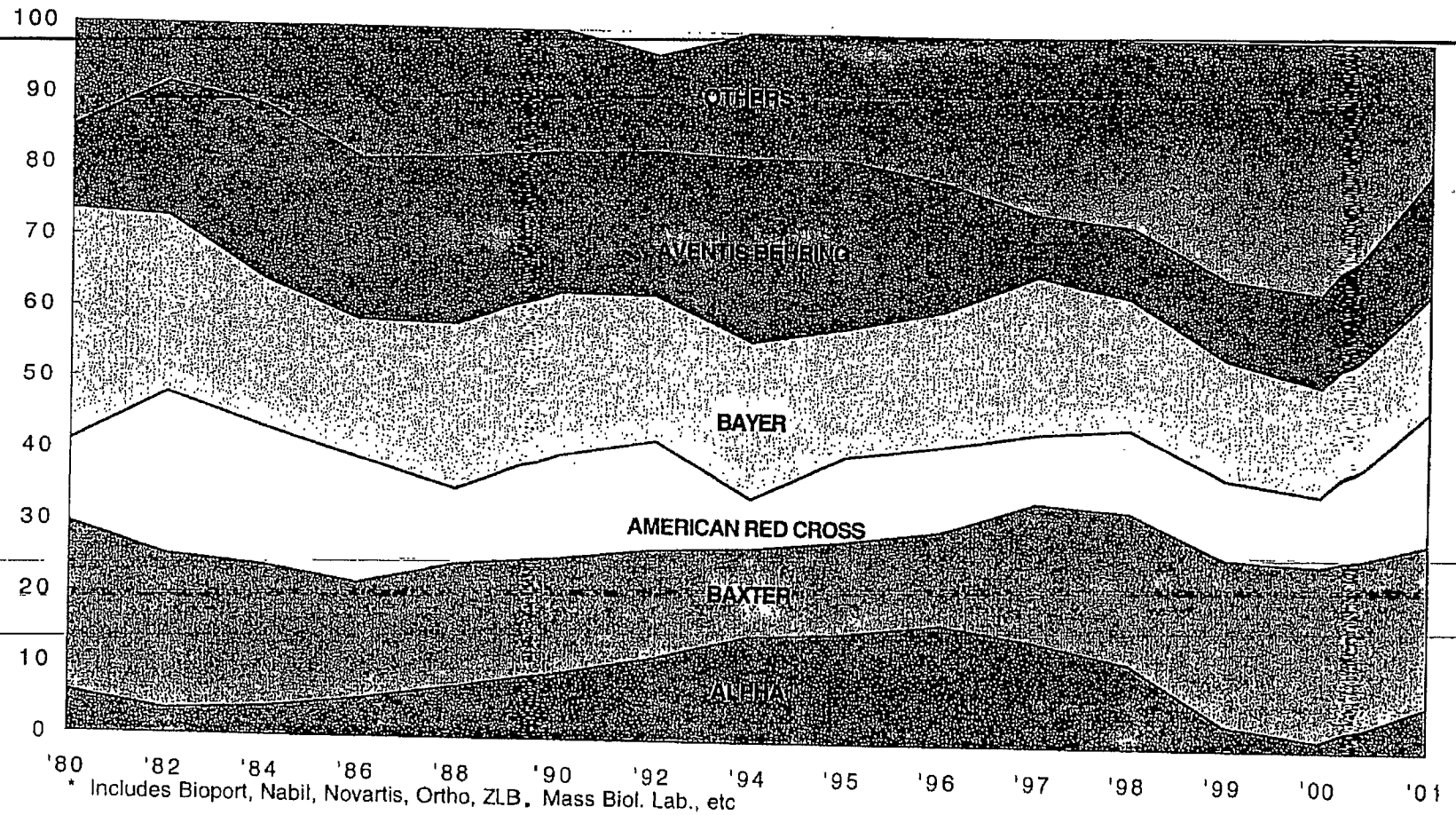
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

MARKET SHARES BY COMPANY - PLASMA PRODUCTS

Based on Sales in Dollars from 1980 to 2001



* Includes Bioport, Nabil, Novartis, Ortho, ZLB, Mass Biol. Lab., etc

The Marketing Research Bureau, Inc.

3) MARKET OVERVIEW

3.1) RESULTS BY PRODUCT LINE

In 2001, the U.S. plasma fractions market reached $2,033.6 million (plasma products only), a 5.7% increase from the previous year ($1,726.4 million), primarily attributed to an increase in prices of several products, in particular IGIV.

When including recombinant Factors VIII, Factor IX, and Factor VIIa, but not RSV monoclonal antibody (Synagis, as was done in 1999), the market reached $2,908.9 million, a 16.6% increase from the previous year ($2,494.3 million without Synagis). The market did not increase as much as it did in prior years because of the shortage of recombinant Factor VIII.

The sales of the recombinant Factor VIII products increased by 10.9% in dollars and 5.4% in units, reflecting a slight price increase, while the sales of recombinant Factor IX posted a modest decline both in dollars and units, possibly attributed to the gains of the plasma-derived Factor IX products which had been unavailable for some time.

In 2001, IGIV was the driving force of the U.S. plasma fractions market with a 24% growth, both in units and in dollars. IVIG sales represented over half of the total plasma products market (51.9%), up three percentage points from the previous year.

In contrast to previous year, the demand for albumin increased by 15.1% in volume but its price continued to decline (-7.3%), causing an overall revenues increase in revenues of 6.7%.

The Plasma Fractions Market in the United States

	Without rFVIII & IX And rFactor VII:a		***With rFVIII & IX And rFactor VII:a***	
Year	*Dollars (Million)*	*Percent Change*	*Dollars (Million)*	*Percent Change*
1987	408.4	+ 6%		
1988	530.0	+ 30%		
1989	671.5	+ 27%		
1990	750.6	+ 12%		
1991	853.1	+ 14%		
1992	956.3	+ 12%		
1993	1,104.8	+ 16%		
1994	1,162.0	+ 5%	1,312.5	+ 10%
1995	1,223.7	+ 5%	1,396.5	+ 6%
1996	1,310.2	+ 7%	1,531.8	+ 10%
1997	1,314.9	-	1,619.7	+ 6%
1998	1,495.2	+ 14%	2,065.7	+ 26%
1999	1,633.8	+ 9%	2,571.8	+ 24%
2000	1,726.4	+ 6%	2,915.7	+ 13%
2001	2,033.6	+17.4%	2,908.9 *	N.A. *

"Synagis", RSV monoclonal antibody is not included from 2001 onward.

Between 2000 and 2001, the sales of the intramuscular immune globulin went down:

- Polyvalent intramuscular immune globulin (IGIM) sales declined both in volume and dollars (-37.2% and –30.8% respectively),
- RhoD immune globulin sales declined by –6.4% in volume but grew by 6.4% in dollars. In 2001, Nabi's "WinRho SDF" was no longer included among the Rh Immune globulin products but treated separately to reflect the usage of this product for ITP
- Hepatitis B immune globulin sales lost -2.5% in volume, and –5.5% in value,
- Rabies immune globulin sales went down (-18.7% in volume, and –10.4% in dollars, due an to over-estimation in 1999.

The sales of CMV, Varicella Zoster and plasma-derived Respiratory Syncytial Virus (RSV) all went down slightly in volume and dollars. Conversely, the sales of RSV monoclonal antibody continued to increase in dollars from 2000, reaching 516 million in 2001. Due to the insignificance of the plasma-derived product, it was decided that this monoclonal antibody product would no longer need to be included in the table.

As many hemophilia patients switched over to a plasma-derived Factor VIII when Kogenate SF was unavailable, the sales of a plasma-derived Factor VIII increased by 50.0% in units and 52.0% in dollars between 2000 and 2001. Yet, the sales of recombinant Factor VIII increased despite the shortage, as Baxter increased its production capacity, and Wyeth sold more "ReFacto". In volume, the sales of recombinant Factor VIII grew by 5.4%, and by 10.9% in dollars. Between 2000 and 2001, the market share of recombinant Factor VIII to the total Factor VIII market fell from 71.8% to 66.0% in dollars and from 65.8% to 58.1% in units.

On the Factor IX market, the sales of the recombinant product faced the progression of Aventis Behring's "Mononine" and, to a lesser extent, of "AlphaNine SD" which became available again. The sales of recombinant Factor IX posted a modest decline of –7.3% in units and –6.1% in dollars from the previous year. Nevertheless, this product continued to dominate the Factor IX market with a 72.8% share. Mononine sales increased by 22.9% in units and 26.5%, and those of AlphaNine SD, by over 300%, as sales in previous years were negligible.

The share of the Factor IX complex concentrates continued to go down (-16.7% in units), partially due to their unavailability. They are no longer used for the treatment of patients with inhibitors. Baxter's "Proplex T" has long been used to treat the few Factor VII-deficient patients but Novo Nordisk's "NovoSeven" has now become the treatment of choice for these patients.

As regards the market for inhibitor products, the sales of recombinant Factor VII:a (Novo Nordisk's "NovoSeven") continued its expansion, its sales reaching an estimated $190 million in 2001. Hyate:C sales tumbled from $20 million in 2000 to about $7.0 million in 2001 while

the sales of Nabi's "Autoplex T", decreased by –33.3% in units and those of Feiba VH increased slightly (+8.3% in units).

The sales of Alpha-1 Antitrypsin went down (-17.1% in units and in dollars). The sales of Antithrombin III declined by 18.3% in volume and by –17.1% in dollars.

The fibrin sealant market continued its progression, as market penetration went on. Unit sales went up by 18.3% and dollar sale by only 3.7%, due to a price competition between the two distributors. The unit sales of Baxter's "Tisseel" went up faster than those of Hemacure's "Hemaseel APR" (+25.9% and +0.8% respectively) while the dollars sales of Tisseel went up by only +8.3%, because of the lower prices granted by Baxter. The total commercial fibrin glue market reached an estimated $42.9 million.

In 2001, the following products price changes were observed, all companies combined.

Polyvalent IGIV		
Per Gram	from $47.8 to $48.0	+ 0.5%
Albumin		
12.5 grams vial	from $36.7 to $34.0	-7.3%
Plasma-derived Factor VIII		
International Unit	from $0.44 to $0.45	+ 1.3%
Recombinant Factor VIII		
International Unit	from $0.71 to $0.74	+ 5.2%
Recombinant Factor IX		
International Unit	from $0.73 to $0.74	+ 1.4%
Alpha One Antitrypsin		
Per vial (500 IUs)	$205 (unchanged)	0.0%
Antithrombin III		
International Unit	$0.45 (unchanged)	0.0%
Fibrin Sealant		
Per mL	from $106 to $93.3	- 12.3%

The price erosion affected particularly albumin, as its price went down by about -7%. The product mix has changed significantly in the last few decades, and IVIG sales reached over half of the total market for the first time:

- In 1974, albumin accounted for 46% of the total market. By 2001, fraction V (albumin and Plasma Protein Fraction) represented only 11.4% of the market.
- The market share of IGIV grew from 5% of total revenues in 1984 to 51.2% in 2001.
- In 1974, plasma-derived Factor VIII concentrate represented 14% of the market, and 20% in 1994. Its share began to decline when recombinant Factor VIII appeared, but it rebound in 2001, and the sales of plasma-derived Factor VIII accounted for 14.0% of the total market (without rFVIII), the same as in 1974.

The Plasma Fractions Market in the United States – 2001
Results by Product

Product	Sales ($ Million)	Change '01/'00
Polyvalent & Hyperimmune IGG	$ 230.5	- 3.1%
Polyvalent IGIV	$1,041.9	+ 24.4%
Fraction V	$ 232.4	+ 6.7%
Plasma-derived Factor VIII	$ 284.0	+ 44.9%
Recombinant Factor VIII	$ 552.2	+ 10.9%
Plasma-derived Factor IX	$ 48.3	+ 72.5%
Recombinant Factor IX	$ 133.2	- 6.1%
Factor IX Complex	$ 1.4	- 5.4%
Anti Inhibitor Complex Concentrates	$ 60.3	+ 37.4%
Recombinant Factor VII:a	$ 190.0	+ 55.1%
Antithrombin III	$ 2.7	- 45.5%
Alpha-1 Antitrypsin	$ 89.2	+ 17.1%
Fibrin Sealant	$ 42.9	+ 3.7%
Total with rFVIII and rFIX	$2,908.9	- 0.4%
Total without rFVIII and rFIX	$2,033.6	+ 17.4%

Between 2000 and 2001, the Factor VIII market continued to grow aggressively (about + 20% in units and dollars) to reach close to 1,300 million international units (including about 83 million units for the treatment of von Willebrand's Disease patients. Assuming that there are 13,000 hemophilia A patients, this represented an average annual consumption of about 100,000 units per patient.

Between 2000 and 2001, some 210 million units of Factor VIII were used, despite a shortage of recombinant Factor VIII, in part offset by plasma-derived products. This was attributed to a higher usage level per capita, caused in part by the aging and bodyweight increase of children using recombinant Factor VIII and in part by more extensive secondary prophylaxis. It was also the result of higher on-demand usage, triggered by a higher confidence level on the part of patients and physicians towards the clotting factors available on the market, including plasma-derived Factor VIII. Furthermore, reimbursement from the insurance companies has become easier over the years, in particular for prophylactic treatment, facilitating increased product usage. Demographics, i.e. the number of new hemophilia patients played only a small part in the growth of the Factor VIII market.

The market share of recombinant Factor VIII products declined from 73.6% in 1999 to 66.0% of the total market in dollars in 2001, and from 64.7% to 58.1% in units, due to the shortage of recombinant Factor VIII.

In 2001, the Factor IX market was estimated at 260 million units, a 6.4% growth from the previous year. Genetics Institute's recombinant Factor IX ("BeneFIX") captured 72.8% of the Factor IX market in value (a ten percentage points decline), and 69.2% in volume (-10.3 percentage points).

The sales of Alpha-1 Antitrypsin decreased by 17.1% in volume and in value, due to production slow downs through 2001.

Antithrombin III sales went down in volume and in price (-45.5%), due to lack of interest for the product. The U.S. antithrombin III market remains relatively small in the United States compared with most

western European countries, because of the limited FDA-approved indications and low acceptance on the part of many hematologists.

3.2) RESULTS BY COMPANY

The Plasma Fractions Market in the United States – 2001 Results by Company (With/Without recomb. Factors)

Company	With Recomb. ($ Million)	Without Recomb. ($ Million)	Market Share *
Baxter	$ 905.8	$ 466.6	22.9%
American Red Cross	$ 378.8	$ 378.8	18.6%
Aventis Behring	$ 392.1	$ 345.3	17.0%
Bayer	$ 370.8	$ 336.6	16.6%
Novo Nordisk	$ 190.0	-	N.A.
Wyeth	$ 165.2	-	N.A.
ZLB Bioplasma	$ 133.4	$ 133.4	6.6%
Alpha Therapeutic	$ 130.2	$ 130.2	6.4%
Ortho Clinical Diag.	$ 61.2	$ 61.2	3.0%
Nabi	$ 73.1	$ 73.1	3.6%
MedImmune	$ 33.2	$ 33.2	1.6%
Aventis Pasteur	$ 30.0	$ 30.0	1.5%
Novartis	$ 29.4	$ 29.4	1.4%
All others	$ 15.8	$ 15.8	0.8%
Total	$2,908.9	$2,033.6	100.0%

* Without recombinant products

In 2001 Baxter was the market leader with 22.9% of the total market (plasma-derived products only), followed by the American Red Cross which came in the second place for the first time ever, with 18.6%. The ARC advance was caused by a strong increase in its sales of Factor VIII (approximately +73%). Aventis Behring was in third position with 17.0%, closely followed by Bayer (16.6%). These four companies held 75% of the market, and none the others exceeded 10% market share.

When taking the non plasma-based products into account (recombinant Factor VIII, IX, and VII:a), Baxter was again the leader with 31.1% of total sales, followed by Aventis Behring (13.5), and by the American Red Cross with 13.0%). Bayer was fourth with 12.7%.

As Alpha Therapeutic began to fractionate again in the course of the year, sales results gradually improved, and the company posted the strongest gain between 2000 and 2001 (+225.9%). On the other hand, Bioport ceased its fractionation operations while concentrating on the vaccine business, and nominal sales from this company were recorded in 2001.

The Plasma Fractions Market in the United States – 2001

Change from 2000 to 2001

Company	*With*	*Without*
	Recombinant Products	
Baxter	+27.0%	+ 23.8%
American Red Cross	+ 30.0%	+ 30.0%
Aventis Behring	+2.0%	+ 17.0%
Bayer	- 17.6%	- 10.5%
Novo Nordisk	- 55.1%	N.A.
Wyeth	16.5%	N.A.
ZLB Bioplasma	N.A.	N.A.
Alpha Therapeutic	+225.9%	+225.9%
Ortho Clinical Diag.	+ 15.0%	+ 15.0%
Nabi	+ 3.5%	+ 3.5%
Aventis Pasteur	- 14.5%	- 14.5%
Novartis	- 3.6%	- 3.6%
Total Market	- 0.4%	+ 17.4%

In summary, the 2001 plasma fractions market experienced a relatively strong growth, fueled by the sales of IVIG, Factor VIII and IX. When including recombinant products, the shortage of Bayer's recombinant Factor VIII resulted in a lower growth rate than the plasma products market. Some price increases (IGIV and coagulation factors) were noted, although the price of albumin went down. The manufacturing costs were higher than in previous years because of the higher cost of

plasma and further improvements and investments. These events negatively affected the fractionators' profit margins.

3.3) HISTORICAL DEVELOPMENTS

In the last decade, the market growth resulted from the combination of several factors: new product introductions, (IGIV, new technology Factor VIII and IX, Alpha-1 Antitrypsin, Antithrombin III, fibrin glue), price increases, and volume growth, driven by the population increase and aging, as well as the favorable economic climate. On the other hand, cost containment limited the market expansion. More specifically, the following events characterized the market development during this period:

- From 1986 onward, the increasing acceptance of polyvalent intravenous immune globulin (IGIV), with Sandoz (then Novartis) and Cutter (Bayer) as the initial suppliers of this product,

- In 1987/88, the high priced Factor VIII, following the introduction of monoclonal antibody-purified products from Aventis Behring and Baxter

- In 1988/90, the introduction of IGIV by other companies (Alpha Therapeutic, American Red Cross, Armour (Centeon), Baxter, Immuno, etc), and of Alpha-one Antitrypsin by Miles (Bayer).

- In 1992/93, the introduction by Alpha and Armour of new Factor IX concentrates. Since they contained only the Factor IX molecule, instead of a combination of Factor II, V, VII, IX and X, they soon became the products of choice in the treatment of hemophilia B. Consequently, the "Prothrombin Complex Concentrate (PCC)" products gradually lost market share in favor of the "pure" Factor IX products. However, the latter were more expensive, and the health care bill for the treatment of hemophilia B increased substantially.

- In 1992/93, the introduction by Baxter and Bayer of recombinant Factor VIII concentrate opened a new era for hemophilia A patients, in particular for the "PUPs" and the younger ones. From this year

onward, the plasma products market shifted as IGIV took over the role of the main driving force from Factor VIII concentrate to. This was the consequence of the rapid market acceptance of IGIV, and, at the same time, the declining role of plasma-derived Factor VIII, in favor of recombinant Factor VIII.

- Another five years passed before recombinant Factor IX was approved by the FDA (1997), offering to the hemophilia B patients the same opportunities as to the hemophilia A patients.

- By 1997, the AIDS crisis which had devastated the hemophilia community and negatively impacted on the plasma industry since the mid-1980's was partially resolved, at least from the financial standpoint with the settlement offered by the five manufacturers of Factor VIII suspected of having infected hemophilia patients in the 1980's. In the late 1990's, the Ricky Ray Act brought additional financial relief to these patients and their families.

  In the mid-1990's, a new controversy emerged: Creutzfeldt-Jakob Disease (CJD) became a major cause of concern among users of blood products, physicians and the general public. The manufacturers and the regulatory authorities moved promptly to avoid a second AIDS crisis, and tackled the matter by taking a series of safety measures to ensure the maximum safety of the plasma products. This resulted in a shortage of IGIV and of some other plasma products, leading the authorities to face a difficult choice between safety and product availability. Today, "variant CJD" continues to represent an unknown risk to the patients receiving plasma products.

- In 1999, the approval by the FDA of Novo Nordisk's "NovoSeven" ended the potential dependency of hemophilia patients on plasma-derived products, as those with an inhibitor could now be treated with a non plasma-based anti-inhibitor factor.

- That year, the FDA also approved fibrin glue, allowing surgeons to use a commercial product instead of the "home-brewed" made from autologous plasma.

- In 2000 and 2001, the shortage of Bayer's "Kogenate FS", recombinant Factor VIII resulted in an increase in the sales of the plasma-derived Factor VIII concentrates, as many patients had to resort to this type of product because they were unable to switch to another recombinant product, itself in tight supply. Furthermore, the decrease in the demand of albumin which had been observed in recent years appeared to abate, contributing to the market growth in 2001, even though the price of albumin continued to be depressed.

All these factors contributed to the sustained growth of the US plasma fractions market, from about $400 million in 1986 to over 2.0 billion by 2001.

4) IMMUNE GLOBULIN MARKET

In 2001, total sales of immune globulin products, IV and IM, polyvalent and hyperimmunes combined reached $1,270.8 million, a –18.2% increase over 2000 ($1,075.2 million).

4.1) INTRAMUSCULAR POLYVALENT IMMUNE GLOBULIN AND HYPERIMMUNE GLOBULIN PRODUCTS

4.1.1) POLYVALENT INTRAMUSCULAR IMMUNE GLOBULIN

In 2001, the sales of polyvalent intramuscular immune globulin amounted to $2.8 million, 30.8% lower than in 2000, Bioport no longer produced any IGIM. The army is usually an important client for IGIM.

The sales of intramuscular immune globulin may go up again in the coming years if the subcutaneous administration of immune globulin to treat primary immune deficiencies gains acceptance. This procedure has been largely adopted in the Scandinavian countries – in part due to the temporary unavailability of IGIV at some point in the mid-1980's – and could spread in the U.S. Aventis Behring is currently conducting a clinical trial with "Beriglobin P".

The price of polyvalent IGIM which had remained stable for several decades at around $2.50 for a 2 ml vial averaged $8.00 (2 ml vial, containing 0.33 grams of proteins) in 1996, to jump to $8.50 in 1997 as a result of the solvent detergent treatment of the product at one of the facilities, and to about $16.80 per vial in 1998, and remained unchanged in 1999. In 2001, the average selling price was recorded at $17.00 per vial. Sales were estimated at $2.8 million.

The dosage recommended for pre-exposure prophylaxis against hepatitis A is 0.02 ml/Kg offering protection for three months, or 0.06 ml/Kg, for a five months protection. For post-exposure treatment, the immune globulin is 85% effective in preventing hepatitis A when administered within two weeks following exposure to HAV. The dosage is 0.02 ml/Kg bodyweight.

The Centers for Disease Control and Prevention (CDC) estimate that there are approximately 140,000 HAV infections in the United States each year. The highest rates of the disease occurs among children aged 5-14 years. 26% of them stem from person to person contact, 16% from day care centers, 6% from travel, and 2% from food and water. The origin of the disease is not identified in the remaining 50% of the cases. Hepatitis A is more prevalent in poor, overcrowded environments.

As the vaccines are not recommended for infants, IGIM is still the best prevention for them. The vaccine (e.g. "Havrix") offers protection for up to ten years if a booster shot is administered six months after the initial administration. The cost is about $150.00 for the full course of prophylactic administration.

4.1.2) TETANUS IMMUNE GLOBULIN

The tetanus immune globulin market has remained stable for many years. Bayer is the sole supplier of the U.S. market. In 2001, sales went up in volume (+50%) and in dollars (+54%), to $5.4 million with about 63,000 vials sold.

The average selling price of Tetanus immune globulin increased from $5.00 per vial (250 International Antitoxin Units) in 1991, to about $72.00 in 1999, a strong price increase due to the S/D treatment of "BayTet" which was introduced in late 1996. In 2001, the price was $86 per vial (250 international units). BayTet is administered intramuscular route. No intravenous Tetanus immune globulin is available in the U.S.

An estimated 70% of Tetanus Immune Globulin is used to treat drug abusers and patients over 50. While more than 95% of children entering school since 1980 have received the primary tetanus immunization series, half of persons over age 60 lack the ability to produce necessary protective levels of circulating anti-tetanus toxin antibody.

4.1.3) RABIES IMMUNE GLOBULIN

Sales of rabies immune globulin have increased in recent years as the disease spread among wildlife animals, in particular in the Northeastern United States. However, in 2001, sales of rabies immune globulin went down by 18.7% in volume and –104% in dollars from 2000, to reach $41.6 million. Aventis Pasteur dominated the market (72% market share) with "Imogam", a plasma-derived immune globulin sold along with the vaccine. The average dosage for an adult is 1,500 IUs, or 10 mL.

Post exposure rabies prophylaxis is recommended by the U.S. "Public Health Service Immunization Practices Advisory Committee" and consists of local cleansing of wounds followed by a combined injection of rabies immune globulin and vaccine. According to an article in JAMA (2000; 284;1001), dog bite injuries are the main source of injury in the U.S., representing 81% of all bites. Cats follow with 13, and rabbits with 4%.

Aventis Pasteur has a competitive advantage over Bayer as it supplies both the immune globulin and the vaccine. The World Health Organization recommends a standard dose of 20 IU/kg bodyweight. Outside the United States, Rabies immune globulin of equine origin is available from Aventis Pasteur at a much lower price. However, it reportedly causes adverse reactions in some 6% of the patients.

POLYVALENT INTRAMUSCULAR IMMUNE GLOBULIN

COMPANY	UNITS * (000)	A.S.P. $	DOLLARS (MM)	MARKET SHARE	CHANGE FROM '00	
					UNITS	DOLLARS
Massachusetts Lab.	62	19.0	1.178	42%	-69.0%	-67.3%
Bioport	20	10.0	0.200	7%	-90.0%	-55.6%
Bayer	75	19.0	1.425	51%	N.A.	N.A.
Total	157	17.9	2.803	100%	-37.2%	-30.8%

2 mL equivalent

RHOD IMMUNE GLOBULIN

COMPANY	UNITS * (000)	A.S.P. $	DOLLARS (MM)	MARKET SHARE	CHANGE FROM '00	
					UNITS	DOLLARS
Ortho	765	80.0	61.200	82%	0.7%	15.0%
Bayer	180	75.0	13.500	18%	-28.0%	-20.6%
Total	945	155.0	74.700	100%	-22.5%	-25.0%

* 300 to 320 Micrograms vial

TETANUS IMMUNE GLOBULIN

COMPANY	UNITS * (000)	A.S.P. $	DOLLARS (MM)	MARKET SHARE	CHANGE FROM '00	
					UNITS	DOLLARS
Bayer	63.0	86.00	5.418	100%		
Total	63.0	86.00	5.418	100%	50.0%	53.6%

* 250 IU/vial

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

HEPATITIS B IMMUNE GLOBULIN

COMPANY	UNITS * (000)	A.S.P. $	DOLLARS (MM)	MARKET SHARE	CHANGE FROM '00	
					UNITS	DOLLARS
Nabi	65	500.0	32.500	86%	4.8%	9.2%
Bayer	14	380.0	5.320	14%	-26.3%	-48.1%
Total	79	478.73	37.820	100%	-2.5%	-5.5%

* 5ml (1,560 IU)

RABIES IMMUNE GLOBULIN

COMPANY	UNITS * (000)	A.S.P. $	DOLLARS (MM)	MARKET SHARE	CHANGE FROM '00	
					UNITS	DOLLARS
Aventis Pasteur	150	200.0	30.000	72%	-16.7%	-14.5%
Bayer	33	350.0	11.550	28%	-26.7%	2.7%
Total	183	227.0	41.550	100%	-18.7%	-10.4%

* 2 mL vials (150 units/mL)

OTHER HYPERIMMUNE GLOBULIN

COMPANY	UNITS * (000)	A.S.P. $	DOLLARS (MM)	CHANGE FROM '00	
				UNITS	DOLLARS
MedImmune (1)	71	454.5	32.270	-11.3%	-11.3%
Mass. Lab. (2)	20	122.0	2.440	-55.6%	-59.8%
MedImmune (3)	2	465.0	0.930	-50.0%	-50.0%
Nabi (4)	220	148.0	32.560	5%	11%
Total	N.A.		68.200	N.A.	N.A.

** This table does not include MedImmune's "Synagis" (RSV MoaB). In 2001 Synagis' sales amounted to $516.4 million.
WinRho SDF has been included in this table instead of the RhoD IGG Table because it is used to treat ITP and not to prevent HDN

(1) CytoGam, 2.5 grams in 50 mL vial
(2) Varicella Zoster IGIM, 125 Units vial
(3) RespiGam
(4) WinRho SD

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

SUMMARY OF ALL HYPERIMMUNE IMMUNE GLOBULINS

COMPANY	DOLLARS (MM)	MARKET SHARE	CHANGE 00/99
Bayer	35.788	16%	-14.9%
Ortho	61.200	27%	15.0%
Aventis Pasteur	30.000	13%	-14.5%
Nabi	65.060	28%	10.0%
Mass Lab	3.618	2%	-62.6%
MedImmune *	33.200	15%	N.A.
Total	228.866	100%	N.A.

* Synagis is no longer included among MedImmune products in 2001

4.1.4 HEPATITIS B IMMUNE GLOBULIN

In 2001, the sales of Hepatitis B immune globulin amounted to about $37.8 million, a –2.5% decrease over the previous year in volume. Nabi ("Nabi-HB") held 86% of the market.

Nabi received FDA approval for "Nabi-HB" HB surface antigen (HBsAg)-positive persons, household exposure to hepatitis B immune globulin in 1999. The product is a 5% formulation of hepatitis B immune globulin with high anti-HBV antibody titers, which can be delivered by intramuscular injection only. "Nabi-HB" is indicated for treatment following sexual exposure to persons with acute HBV infection, acute exposure to blood containing HBsAg, and exposure of infants born to HBsAg-positive mothers. In addition to solvent-detergent treatment, "Nabi-HB" is nano-filtered to reduce the risk of viral transmission.

The recombinant hepatitis B vaccines are so efficient that a small dose is enough to protect an individual but it does not produce enough antibodies to increase the plasma titer in a vaccinated plasma donor. Hyperimmune hepatitis B plasma from donors who have been immunized with a recombinant hepatitis B vaccine often cannot be used to make hyperimmune hepatitis B immune globulin because of this low titer. Merck's plasma-derived "Heptavax-B" vaccine had 15 nanograms of hepatitis B vaccine and this was enough to boost the donor's plasma and produce sufficient antibodies. For this reason, the price of hepatitis B hyperimmune plasma has gone up in recent years

The Centers for Disease Control recommend that high risk groups be vaccinated against Hepatitis B. However, the comparatively high cost of the three doses ($100 each) necessary to create immunity may be an obstacle for low income people at risk.

The vaccine provides active immunization which does not eliminate the need for passive activity, among some moderate risk individuals and as an initial protection among high risk groups during the time necessary for the vaccine to produce active immunity. Therefore, the vaccines may represent only a limited obstacle to the immunoglobulin market expansion.

There are approximately 12,000 cases of Hepatitis B infections each year in the U.S. However, the disease is underreported, and the actual incidence of hepatitis B cases is probably higher. Worldwide, hepatitis B is among the most common infectious diseases.

Since the early 1990's, increases in HBV infections have been observed in three significant risk groups: sexually active heterosexuals, homosexual men, and injection drug users. According to CDC estimates, the overall rate of HBV new infections has steadily declined from more than 300,000 persons in the 1980s to some 200,000 persons in 2001, as routine hepatitis B vaccination for newborns and at-risk occupational groups continues to expand at the encouragement of public health policy officials.

Perinatal transmission to newborns by infected mothers is another sub-market representing about 22,000 potential cases. Without medical intervention, about 80% will be infected by blood or mucous membrane exposure. Even if they are not infected during the perinatal period, children of HBV-infected mothers remain at high risk of acquiring chronic HBV infection by person-to-person (horizontal) transmission during the first 5 years of life.

More than 90% of these infections can be prevented if HBsAg-positive mothers are identified so that ideally their infants can receive hepatitis B vaccine and hepatitis B immune globulin (HBIG), together with the first of three doses of recombinant hepatitis B vaccine, within 12 hours after birth (5% to 15% of HBV transmission occurs in utero).

Between 10% and 15% of all orthoptic liver transplant procedures are performed in patients whose own liver eventually became cirrhotic or cancerous as the result of chronic hepatitis B infection. These patients are unable to mount or sustain an effective immune response to their endogenous hepatitis B. Without effective continuing immunoprophylaxis, a new healthy donor liver can become quickly infected with HBV, particularly as these patients must be maintained on a powerful immunosuppressive regimen to prevent graft rejection.

The Canadian company filed a Biologics License Application with the U.S. FDA for its anti-hepatitis B hyperimmune globulin product. The Canadian biopharmaceuticals firm is seeking approval to use the product for postexposure prevention of hepatitis B infection.

4.1.5) RHOD IMMUNE GLOBULIN

In 2001, the sales of RhoD immune globulin in the United States amounted to approximately $74.7 million, a 6.4% decrease from 2000 ($70.2 million). Unit sales of Ortho's "RhoGam Ultra-Filtered" remained stable while those of Bayer's "BayRhoD" went down by 22.5%. As it does not compete on the Hemolytic Disease of the Newborn (HDN) market, Cangene/Nabi's "WinRho S/D" sales were reported in another group of products.

The HDN market is essentially stable in the United States, growing by 1% per year. Approximately 70% of Rh immune globulin administration is performed made in the hospital setting, and 30% in the OB/GYN's offices although the latter sub-market is growing at the expense of the hospital market. Furthermore, dispensing has moved from the hospital blood banks to the hospital pharmacy.

The mini-dose syringe (50 mcg) is practically no longer used today. The full-dose (300 mcg) presentation is administered twice, ante-partum at a non-hospital location and post-partum upon delivery at the hospital.

Four organizations distribute Rh Immune Globulin in the United States: UBS, Infolab, ASD, NSS and Henry Schein.

In 1997, Ortho introduced a virus inactivated product using a filter, which screens both the lipid enveloped and non-enveloped viruses. The product called "RhoGam UF" (Ultra Filtered)" was launched at $86.00/vial (300 mcg).

4.1.6) CMV INTRAVENOUS IMMUNE GLOBULIN

In 2001, the sales of MedImmune CMV IGIV ("CytoGam") amounted to about $32.3 million, a –11.3% decrease from 2000. "CytoGam" was launched in 1991 by Connaught and received Orphan Drug status. In 1992, it was sold to MedImmune for $4.5 million and royalties on sales. It is manufactured by the Massachusetts Public Health Biologic Laboratories until MedImmune starts its production at its own plasma fractionation facility in Frederick, Maryland. Once completed, this plant will be able to produce both polyclonal and monoclonal antibody products including CytoGam, RespiGam (RSV IG), Synagis (RSV MAB) and other products. In 20002, MedImmune plant was approved by the FDA, and the company began producing Cytogam.

CMV immune globulin is indicated for transplant patients who undergo immunosuppressive therapy for bone marrow, stem cell, liver, kidney, pancreas and heart transplants, and for advanced AIDS patients.

The market is expected to continue to grow to include most CMV-negative BMT/stem cell and solid organ transplant patients receiving CMV-positive allografts. The recommended dosage is 150 mg/kg loading dose, followed by biweekly doses of 100 mg/kg, possibly with tapering to 50 mg/kg after week 12.

4.1.7) VARICELLA-ZOSTER IMMUNE GLOBULIN

Varicella Zoster Immune Globulin (VZIG-intramuscular) is used for the prevention and treatment of chickenpox. It is indicated for immuno-suppressed children and adults, pregnant women with exposure to varicella, and newborns and premature infants at risk of or who develop chickenpox. Candidates for VZIG administration are those patients who have not been vaccinated or were unable to develop satisfactory anti-VZV antibody titers after their vaccination. The demand for VZIG will probably continue to decline as more susceptible children and adults without prior chickenpox history are identified and vaccinated.

Varicella leads to 14,000 hospitalizations and 100 deaths in the U.S. every year, with children accounting for 60% of the hospitalizations and 40% of the deaths. The immune globulin is used for prophylactic and therapeutic purposes, as the vaccine is believed to be only 70% to 90% effective.

VZ immune globulin is manufactured by the Massachusetts Biologic Laboratories from plasma collected by the Red Cross Blood Services, Northeast Region, and distributed by FFF Enterprises. In 2001, sales of VZ immune globulin amounted to $2.4 million, a -55.6% decline from 2000, possibly attributed to vaccination against Varicella Zoster.

4.1.8) "WINRHO S/D" AND THE IDIOPATHIC THROMBOCYTOPENIC PURPURA

In 2001, the sales of "WinRho S/D" increased by 4.8% in volume and +10.7% in dollars.

In 1998, Cangene/Nabi launched a new formulation of WinRho SD with a microfiltration step for virus elimination, in addition to the product's initial solvent detergent viral inactivation. "WinRho SDF," which is indicated for treatment of immune thrombocytopenic purpura (ITP), is available in 300 and 1,000 mcg vial sizes. "WinRho SDF's" orphan drug status for the ITP indication will expire in mid-2002, but some competitive products has been reported as seeking FDA approval for this indication.

The Average Wholesale Price (AWP) of WinRho SD was initially $160 for the 300 micrograms size and $70 for the 120 micrograms size. In 1998, the price of the 300 mcg size went down to about $110.00. In 1999, it went up again to $142.40 for the 300 mcg vial size, and $62 for the 120 mcg size.

In the treatment of ITP, 10 vials of 300 micrograms are required for an adult weighing 60 kilograms. The cost of therapy with WinRho SDF is therefore lower than using polyvalent IVIG.

4.1.9) STAPH AUREUS IMMUNE GLOBULIN

"Nabi-Altastaph" is a hyperimmune intravenous immune globulin developed by Nabi Biopharmaceuticals, and containing high levels of Staph Aureus. It is indicated for the treatment of immuno-compromised patients, and individuals who are at risk of short term infection who do not respond immediately to a vaccine. The product is expected to be in phase III clinical trial shortly.

4.1.10) "SYNAGIS" (RESPIRATORY SYNCYTIAL VIRUS MONOCLONAL ANTIBODY) AND RSV IMMUNE GLOBULIN

In 2001, sales of Synagis amounted to $516.4 million, a 20.9% increase from the previous year. As a result, the sales of RespiGam, the plasma-derived equivalent, was to less than $1.0 million.

The respiratory syncytial virus (RSV) is a major cause of pneumonia and bronchiolitis in infants, causing over 90,000 hospitalizations and 4,500 fatalities per year in the US. Synagis can be delivered by intramuscular or subcutaneous injection. It is distributed by Abbott Laboratories in the U.S.

4.1.11) BOTULISM IMMUNE GLOBULIN

In 1999, the Massachusetts Biologics Laboratory developed a Botulism IVIG prepared from the plasma of donors stimulated with the virus. This program, sponsored by the California Department of Public Health, operates under an Investigative New Drug status, and is not intended for large scale commercialization.

The population targeted for this hyperimmune IVIG is limited to about hundred individuals, half of whom reside in rural California. Botulism cases were brought to the attention of the Department of Public Health by rural workers making their own honey without observing the minimum safety precautions. The product is still awaiting FDA approval.

4.1.12) SMALLPOX IMMUNE GLOBULIN

The Massachusetts Biologics Laboratory has a contract with the U.S. Department of Defense to produce small quantities of Smallpox Immune Globulin to treat individuals who might react to vaccination. This product is not intended to be commercialized.

4.1.13) PERTUSSIS IMMUNE GLOBULIN

Pertussis immune globulin was an intramuscular product manufactured and sold by Bayer until the mid-1980's in the United States. The DPT vaccine virtually eliminated the disease almost entirely, thus eliminating the needs for a commercial Pertussis immune globulin. The Massachusetts Biologics Laboratory has manufactured some lots of this product, as a small number of cases still occur. An intramuscular immune globulin was in clinical trial but the limited number of patients made enrollment difficult.

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

POLYVALENT INTRAVENOUS IMMUNE GLOBULIN (IGIV)

COMPANY	UNITS * (000)	KILOS	ASP/vial * $	ASP/gram $	DOLLARS (MM)	MARKET SHARE	CHANGE FROM '00 UNITS	CHANGE FROM '00 DOLLARS
Bayer	1,410	3,525	135.00	54.00	190.350	18.3%	-7.2%	-3.7%
ZLB Bioplasma	1,050	2,625	106.25	42.50	111.563	10.7%	N.A.	N.A.
Alpha Therapeutic	600	1,500	127.50	51.00	76.500	7.3%	189.9%	173.8%
Aventis Behring	1,350	3,375	115.00	46.00	155.250	14.9%	11.1%	11.1%
Baxter	1,950	4,875	124.25	49.70	242.288	23.3%	13.4%	18.6%
Novartis	280	700	105.00	42.00	29.400	2.8%	-69.9%	-71.9%
Am. Red Cross (1)	1,550	3,875	117.50	47.00	182.125	17.5%	66.7%	66.7%
Am. Red Cross (2)	495	1,238	110.00	44.00	54.450	5.2%	1.0%	1.0%
Total	8,685	21,713	119.97	47.99	1,041.925	100.0%	23.9%	24.4%

* 2.5 grams equivalent (50mL 5% concentration)

(1) Polygam SD
(2) Panglobulin

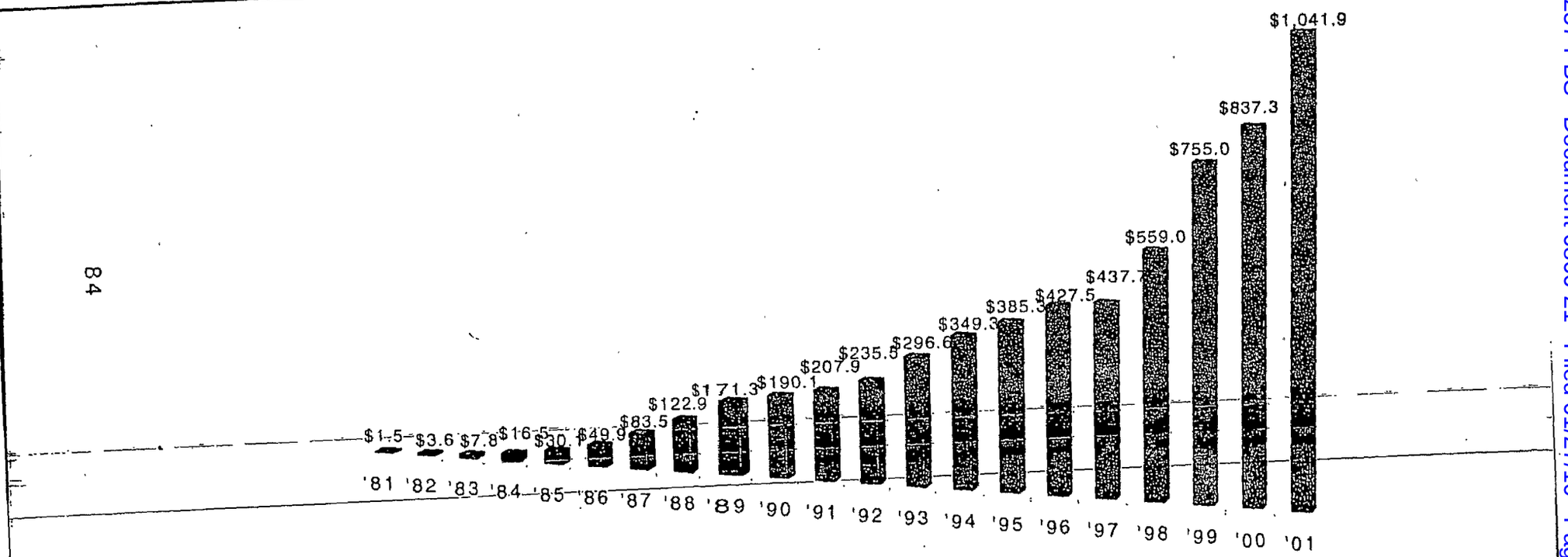
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

THE POLYVALENT INTRAVENOUS IMMUNE GLOBULIN (IGIV) MARKET IN THE UNITED STATES FROM 1984 TO 2001 ($MM)

	1984	1986	1988	1990	1992	1994	1995	1996	1997	1998	1999	2000	2001
Bayer	12.2	18.8	53.7	84.4	98.8	127.2	108.0	124.7	148.8	108.6	206.8	197.6	190.4
Novartis	4.3	27.6	43.8	58.2	51.8	78.0	76.3	61.2	67.1	104.6	139.1	104.6	29.4
Baxter	-	3.5	18.4	24.1	30.7	22.8	51.7	48.8	49.4	88.1	105.1	204.3	242.3
Alpha Therapeutic	-	-	-	9.5	22.0	60.6	74.3	101.5	111.6	131.6	49.9	27.9	76.5
American Red Cross	-	-	7.0	11.0	16.8	4.6	15.8	41.0	42.5	90.4	159.5	163.2	236.6
Aventis Behring	-	-	-	-	10.6	53.0	56.3	48.3	16.2	35.2	94.6	139.7	155.3
ZLB Bioplasma	-	-	-	-	-	-	-	-	-	-	-	-	111.6
All Others	-	-	-	2.9	4.8	3.1	3.1	2.1	2.1	0.5	-	-	-
Total Market ($ Millions)	16.5	49.9	122.9	190.1	235.5	349.3	385.5	427.5	437.7	559.0	755.0	837.3	1041.9
(Units 2.5 grams x000)	178	550	1,510	2,659	3,731	5,484	6,050	6,620	6,560	6,220	6,680	7,012	8,685

THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

POLYVALENT INTRAVENOUS IMMUNE GLOBULIN (IGIV) SALES FROM 1981 TO 2001 $(MM)



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THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

POLYVALENT INTRAVENOUS IMMUNE GLOBULIN (IVIG) SALES
From 1981 to 2001 (2.5 Grams x 000)

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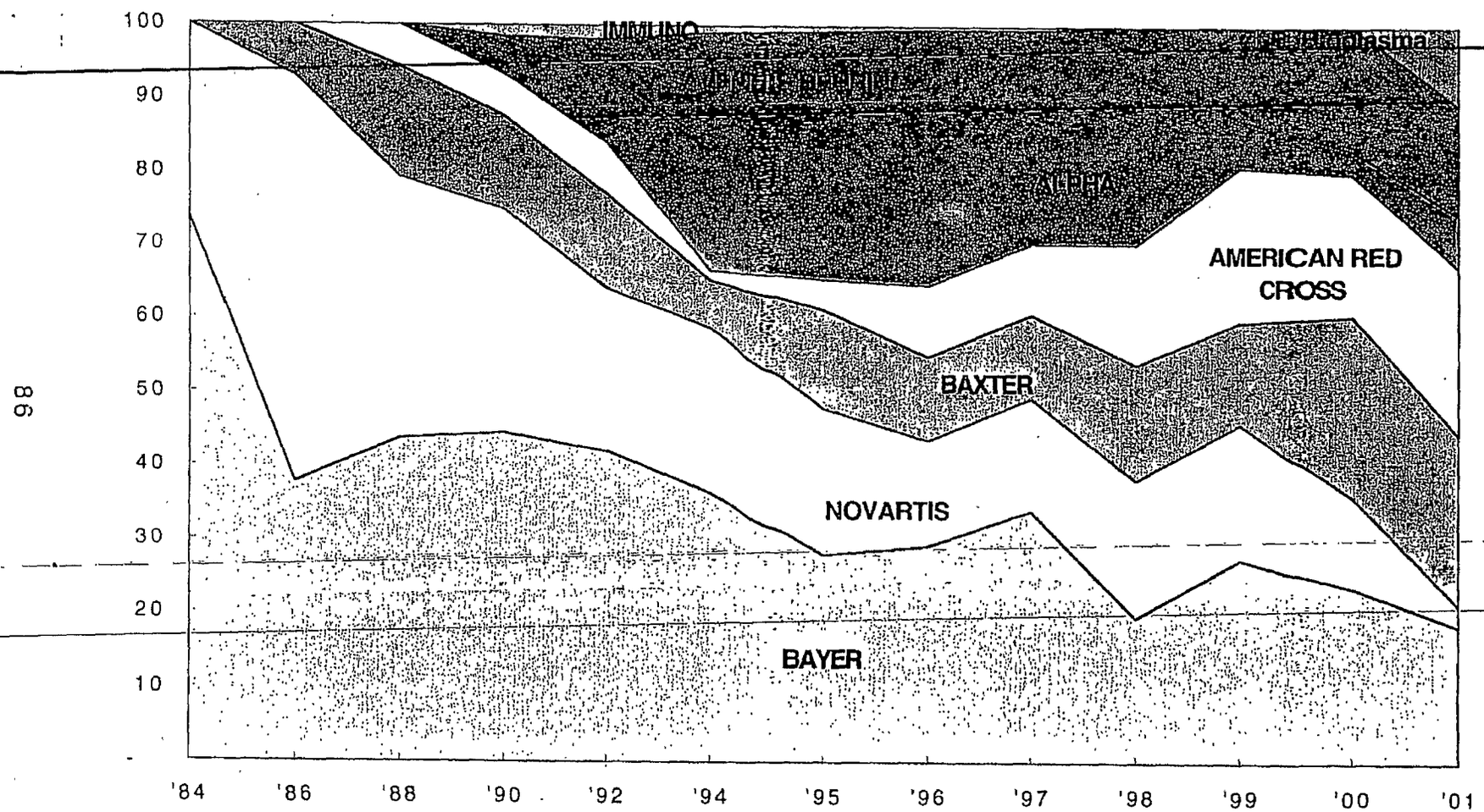
THE PLASMA FRACTIONS MARKET IN THE UNITED STATES - 2001

POLYVALENT INTRAVENOUS IMMUNE GLOBULIN (IVIG)
Market Shares Based on Sales in Dollars



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4.2) POLYVALENT INTRAVENOUS IMMUNE GLOBULIN MARKET (IGIV)

4.2.1) MARKET DEVELOPMENTS

In 2001, the IGIV market reached $1,041.9 million, a 24.4% increase in dollars from 2000 ($837.3 million). In volume, the market increased by 23.9%, an exceptionally high rate of growth, attributed to a "re-building" of the inventory (or "pipeline filling"), after the shortage of the late 1990's, and the increased production undertaken by the manufacturers to remedy to the shortage. The end-user's demand while growing did not increase at such a strong pace in such a relatively short period of time. In particular, it is believed that the patients and physicians have become more conservative in their products usage, as they are now afraid of a newshortage situation: to the extent possible they space out infusion, reduce dosage, possibly use other therapies, but overall demand has not increase more than 10%, or less. Furthermore, a 0.5% average price increase was noted between 2000 and 2001.

Another important event which marked the recent years was the acquisition of the Central Laboratory of the Swiss Red Cross (ZLB) by the Australian firm CSL Bioplasma. As a result of this acquisition, the distribution agreement between the ZLB and Novartis was terminated in the United States from 2001 onward, and mid-2002 elsewhere.

In the course of 2001, the distribution of the product made by the ZLB was therefore transferred to a new company called "ZLB Bioplasma, Inc" which offered a product with initially had a generic name "ZLB IGIV", to be renamed "Redimmune" in 2002, and which was identical to Sandoglobulin. In 2001, Novartis sold the remainder of its inventory of Sandoglobulin.

These events did not affect the production and distribution of Panglobulin by the American Red Cross.

In 2003, two new IVIG products are expected to be licensed by the FDA and could be introduced on the US market: Grifols' "Flebogama" and

Octapharma's "Octagam", both of which have been in clinical trial in the US for several years, under a revised FDA protocol which would somewhat facilitate and expedite licensure.

In 2001, the Immune Deficiency Foundation organized its first national conference. This non-profit association began to play an important role and to become increasingly influential. Similar to the National Hemophilia Foundation some twenty years ago, the IDF will possibly contribute to increasing the supply, safety and quality of IGIV preparations in the United States in the coming years by raising the patients' awareness of IGIV's availability. Similar organizations exist elsewhere, in particular in Canada and in the UK, but the U.S. movement is important because the U.S. feature the highest IGIV consumption level per capita in the world.

IVIG Consumption in selected Countries

Country	*Grams of IVIG used per Thousand Population (2001)*
United States	63.7
Germany	46.6
Australia	45.5
Italy	30.6
Israel	28.6
Japan	28.4

As mentioned earlier, part of the IGIV market could be cannibalized by the intramuscular presentation of polyvalent immune globulin if the subcutaneous administration of this product gains acceptance. Aventis Behring is currently conducting a clinical trial in which 60 patients with primary immune deficiency are infused subcutaneously with "Beriglobin P".

In 2001, 21.7 metric tons of IGIV were used in the U.S. or 21.7 million grams. The average selling price for all products combined remained stable from previous year ($47.00 vs. 47.76 per gram in 2000).